Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/1/2016 11:49:06 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on nomenclature

Michal- I sent them just to you so you could share as appropriate. Some were just yours and I didn't want to mix them up. Thanks,
Sven

On Apr 1, 2016, at 7:39 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thank you and very sorry for the interruption.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 01, 2016 7:30 PM
To: Freedhoff, Michal (Markey)
Subject: Fwd: Sen. Markey TSCA TA on nomenclature

Michal- TA on nomenclature. Thanks,
Sven

Question; **there is a concern being expressed by the House side that the statutory mixture language (even with the modification options I sent you last week) would allow new chemicals to avoid section 5 treatment. What follows below is a draft of a savings clause that would apply to the statutory mixture provisions that is intended to ensure that does not happen. Does it work?**

EPA Response: The House concern is valid. The purpose of the statutory mixture provisions in the current Inventory is to shield from section 5 review chemicals that would otherwise be considered new and require section 5 review. There have been disagreements between EPA and the regulated community over the scope of the statutory mixtures (and other facially broad inventory listings), and (A)(iii) of the Senate bill appears designed to resolve those disagreements. A savings clause that exempts chemical substances not included on the inventory will only beg the question of what chemical substances are included within the six listed statutory mixtures (and what the purpose of (A)(iii) is). In addition, it is not clear currently that a chemical must be included in the statutory mixture to be covered by the statutory mixture listing -- the six listings have different scopes, so it's hard to generalize. Furthermore, by specifically targeting

8(b)(3)(A)(iii) as the problematic part of 8(b)(3), this language would suggest by implication that Congress intends 8(b)(3)(B)(i) to allow chemical substances to be moved onto the Inventory without PMN review, by a process of "rely[ing] on" unspecified guidance documents. (Finally, per earlier TA, the "including but not limited language" in the bill will cause confusion about what other materials might be considered statutory mixtures, and the bill provides no guidance.)

Finally, just a general question about class 2 and the Soap and Detergent assoc nomenclature system – how many substances are included on these lists right now? Is EPA contemplating changing these, and if so, what sort of resources would be required to do so? General response is fine on this one.

A quick search of the non-CBI TSCA Inventory (as of January 20, 2016) revealed 316 chemical substances that indicated (in the Chemical Substance Definition field) that "[t]his substance is identified" by a "SDA Substance Name." 13,776 chemical substance are listed as Class 2 Chemical substances of Unknown or Variable Composition, Complex Reaction Products and or Biological Materials (i.e., UVCBs). Some of the SDA chemicals are a subset of the UVCB chemicals, but not all. EPA has no current plans to change its practice of allowing chemical substances to be identified by UVCB names. EPA has no current plans in place to change the current system of assigning SDA names. Since retroactive changes to the definitions of what is and is not on the Inventory would have the potential to affect the scope of future PMN reviews, determining whether they are warranted would likely be a labor-intensive process.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 1, 2016 at 10:43:07 AM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: nomenclature

Sven

A couple of things on nomenclature – first, wondering if you are close to getting the pending nomenclature TA done?

Second, there is a concern being expressed by the House side that the statutory mixture language (even with the modification options I sent you last week) would allow new chemicals to avoid section 5 treatment. What follows below is a draft of a savings clause that would apply to the statutory mixture provisions that is intended to ensure that does not happen. Does it work?

> "Notwithstanding subparagraph (A)(iii), a chemical substance that is a component of a mixture identified in subparagraph (A)(iii) shall be subject to Section 5 when not present in such mixture and if such chemical substance is not included on the list established in paragraph (1)."

Finally, just a general question about class 2 and the Soap and Detergent assoc nomenclature system – how many substances are included on these lists right now? Is EPA contemplating changing these, and if so, what sort of resources would be required to do so? General response is fine on this one.

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 7:21:49 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Section 26

Michal – got it - checking. Thanks,
Sven

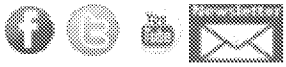
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 3:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: SEction 26

Can you pls turn this around quickly? Not tons of changes from last time you saw it, but includes a lot of the feedback you provided before.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/28/2016 1:12:07 AM
To: Jacqueline Cohen [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA request on rule making procedures

Jacqueline,
This TA responds to the request on rule making procedures.

Pasted below, for ease of reference, is the bill provision you are inquiring about (sec 6(c)(3)). You ask two questions.

1. Why does the text provide that references to 556 and 557 in 553 are disregarded?

Response: This is text from current TSCA, and we do not know why it was included. It seems unnecessary, since the references to 556 and 557 in 553 merely provide that 556 and 557 procedures will apply rather than 553 procedures where a statute requires rulemaking to be on the record, and TSCA does not require rulemaking to be on the record. A reasonable guess is that, because existing TSCA 6(c)(3) provides for informal hearings, including opportunity for cross-examination, Congress may have wanted to be clear that these hearing provisions did not convert the rulemaking into one that is "on the record". If that was the reason for including this language, then it would be even more unnecessary under the bill, since the informal hearing provisions have been dropped.

2. Are the subparagraphs redundant with the APA?

Response: They are largely redundant but not completely. Subparagraph (A) requires a section 6(a) proposal to state with particularity the reasons for the proposed rule, whereas APA 553 requires only a general notice of proposed rulemaking. Beyond that, we do not see any requirements in this paragraph that would not apply anyway under the APA. Again, it may be that the main reason for including all of (3) in current TSCA was to add the informal hearing requirements. Congress may have felt the need, in adding the hearing requirements, to specify that the rulemaking would otherwise proceed under 553. So, again, these provisions may be more unnecessary under the bill than they are under current TSCA.

6 ''(3) PROCEDURES.—When prescribing a rule
7 under subsection (a) the Administrator shall proceed
8 in accordance with section 553 of title 5, United
9 States Code (without regard to any reference in such
10 section to sections 556 and 557 of such title), and
11 shall also—
12 ''(A) publish a notice of proposed rule-
13 making stating with particularity the reason for
14 the proposed rule;
15 ''(B) allow interested persons to submit
16 written data, views, and arguments, and make
17 all such submissions publicly available;
18 ''(C) promulgate a final rule based on the
19 matter in the rulemaking record; and
20 ''(D) make and publish with the rule the
21 determination described in subsection (a).'';

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On Apr 27, 2016, at 4:57 PM, Cohen, Jacqueline <jackie.cohen@mail.house.gov> wrote:

Sven,

Can you get us some TA on paragraph (3) on page 48 of the discussion draft you saw (April 22nd version)? We are wondering why the references to 556 and 557 are disregarded and whether the subparagraphs are redundant with the APA?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 7:48:27 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA on nomenclature

checking

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, March 11, 2016 2:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: SEPW TSCA TA on nomenclature

Thanks - any ta you can provide on who are "workers?" does it mean people who manufacture with the raw chemical or anyone with a job from mowing laws to working at a restaurant.

Thinking in the context of our vulnerable populations definition.

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 2:41 PM
To: Karakitsos, Dimitri (EPW)
Subject: RE: SEPW TSCA TA on nomenclature

Dimitri, heads up that we provided overlapping TA on the same subject to Michal. She framed the request a little differently, EPA's TA is consistent. Please let me know if ok to share this TA with Michal. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 12:13 PM
To: 'Karakitsos, Dimitri (EPW)' <Dimitri_Karakitsos@epw.senate.gov>
Subject: SEPW TSCA TA on nomenclature

Dimitri, this responds to your TA request on nomenclature. Please let me know if any questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

1. **Is the Senate nomenclature language, both Class 2 and statutory mixtures, simply codifying EPA's current practice with regards to those substances?**

   EPA interprets section 8(b)(3)(A)(i) as a requirement to continue its current practice of allowing Class 2 chemical substances to be named and listed as discrete entries on the TSCA Inventory. EPA also interprets this provision as allowing EPA to retain technical discretion to ensure that Class 2 chemical naming is done correctly.

   Similarly, EPA interprets section 8(b)(3)(A)(ii) as a requirement to continue its current practice of allowing Class 2 chemical substances to be named according to the SDA nomenclature system. EPA also interprets this provision as allowing EPA to retain technical discretion to ensure that SDA naming is done correctly.

   EPA interprets section 8(b)(3)(A)(iii) as a statutory ratification of the scopes of these particular Inventory listings, as listed in the TSCA Inventory, in a manner consistent with appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a). However, the phrase "including, without limitation" could be interpreted to broaden the scope of statutory mixtures currently recognized by EPA. If the intent is to simply codify EPA's current practice, it should be clarified that the list of (I) through (VI) is an exclusive list. Further, while EPA can interpret the phrase "all components of categories that are considered to be statutory mixtures under this Act," the phrasing is awkward and it could be improved to reduce the chance of confusion. The following would be clearer: "all chemical substances described by the following category listings, when manufactured as described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)."

   EPA's interpretation of 8(b)(3)(B) is that this provision is wholly inoperative, since EPA is not aware of any "existing guidance" that would trigger 8(b)(3)(B)(i), or duplicate listings on the Inventory that would implicate 8(b)(3)(B)(ii). If this provision is not inoperative, the legislative history in the Senate Committee Report reflects a clear intent that it do something other than merely codify EPA's current practices. Specifically, the Report asserts on page 20 that currently "numerous nomenclature conventions exist that may prevent the efficient distribution of chemicals into commerce," and it explains that the nomenclature provisions "will resolve these issues" by establishing new requirements for EPA. The Report also indicates that the nomenclature provisions will "enable[] similar substances to rely on the Inventory listing of an existing substance." This appears to be a reference to narrowing the scope of substances that will require review under Section 5, due to nomenclature changes.

2. **Is EPA aware of widespread (or any instances) where current Class 2 or statutory mixture language has been abused or used to circumvent Section 5 by allowing entirely new chemicals to market without going through the pmn process?**

   EPA has taken a limited number of enforcement actions related to overly broad interpretation of the coverage of Class 2 chemicals on the Inventory. In addition, many manufacturers have sought confirmation from EPA that chemicals they intend to manufacture are covered by Class 2 chemicals on the Inventory and not subject to PMN requirements. In many of these cases, the Agency has responded that PMNs would be required.

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, March 03, 2016 1:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA on nomenclature

Sven – there seems to be continued confusion over the Senate's nomenclature provisions. I know you all are working on a lot for us and we appreciate it but wanted to ask if someone could fairly quickly respond to two specific questions that are designed to be easy answers.

1. Is the Senate nomenclature language, both Class 2 and statutory mixtures, simply codifying EPA's current practice with regards to those substances?
2. Is EPA aware of widespread (or any instances) where current Class 2 or statutory mixture language has been abused or used to circumvent Section 5 by allowing entirely new chemicals to market without going through the pmn process?

Any help with this would be much appreciated.

Thanks,

Dimitri

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 5:52:11 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: TSCA TA on HLC section 14 (4-18)
Attachments: Markey.TSCA TA.section 14 Senate to House (4-18).docx

Michal, Jonathan and Adrian,
The attached TA responds to the request to compare section 14 - SLC and HLC (4-18) versions. Next up - section 26.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.
Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

[DISCUSSION DRAFT]

SEC. ❚❚. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) IN GENERAL.—Except as provided in this section, thatthe Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (c) are met.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

"(b) INFORMATION NOT PROTECTED FROM DISCLOSURE.—

"(1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Subsection (a) does not prohibit the disclosure of information that is not protected from disclosure under this section on the basis that such information contains information described in subsection (a), subject to the condition that the Administrator shall protect from disclosure the information described in subsection (a) in disclosing the information that is not protected from disclosure.

"(2) øDATAé FROM HEALTH AND SAFETY STUDIES.—ø*Subject to paragraph (1),*é subsection (a) does not prohibit the disclosure of—

"(A) any health and safety study which is submitted under this Act with respect to—

"(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or

"(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and

"(B) any ødataé reported to, or otherwise obtained by, the Administrator from a health

Commented [A1]: This revised version of this paragraph is problematic. By saying that (a) does not prohibit the disclosure of unprotected information on the grounds that such information contains information described in (a), it indicates that (a) information is something other than (b) information. In fact, (b) is a carveout from (a), and information that (b) requires to be disclosed may well be information described in subsection (a). The effect of this provision seems to be that all (a) information that appears in (b) information must be withheld, which largely renders (b) inoperative.

Commented [A2]: This is not in SLC and is problematic, for the reason stated in above comment.

and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the ørelease¿ of any ødata¿ which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the ørelease¿ of ødata¿ disclosing the portion of the mixture comprised by any of the chemical substances in the mixture. *øthis is copied exactly from existing law. should 'data' be updated to 'information' and 'release' be changed to 'disclosure' to conform with the rest of the bill?¿*

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—*øSubject to paragraph (1),¿* subsection (a) does not prohibit the disclosure of—

"(A) a risk evaluation published under section 6;

"(B) any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges; or

Commented [A3]: Not different from the Senate version. We are fine with the wording changes suggested here.

Commented [A4]: Problematic per comment above.

"(C) a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) BANS AND PHASE-OUTS.—

"(A) IN GENERAL.—If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out with respect to a condition of use of a chemical substance or mixture, the protection from disclosure of any information under this section with respect to the chemical substance or mixture shall be presumed to no longer apply, subject to subsection (g)(1)(E) and subparagraphs (B) and (C).

Commented [A5]: It seems confusing that this has now been changed to state, as the general case, that *any* information relating to a chemical for which a single use has been banned or phased out shall presumptively be released, and then to use the limitations in B to make the fairly intuitive point that only information relating to that use should be disclosed.

"(B) LIMITATIONS.—

"(i) CRITICAL USE.—In the case of a chemical substance or mixture for which a specific condition of use is subject to øan exemption pursuant to section 6(f)¿ ø *'critical use' exemptions; need to check this ref-*

erence¿, if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any conditions of use of the chemical substance or mixture which the exemption does not apply.

"(ii) EXPORT.—In the case of a chemical substance or mixture for which there is manufacture, processing, or distribution in commerce that meets the conditions of section 12(a)(1), if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to øany other manufacturing, processing, or distribution in commerce¿ ø*is this correct? or should it be 'any condition of use other than such manufacture, processing, or distribution in commerce'?*¿ of the chemical substance or mixture, un-

Commented [A6]: Confusing, because (A) applies only to a specific use. This seems to literally say that, if EPA bans one use, and exempts one use, the presumption of disclosure applies to all uses other than the exempt one, even though most of them are not banned.

Commented [A7]: Need "to" before "which"

Commented [A8]: Again, suggests that all information relating to all uses but the export use should be released, even though only one use has been banned.

Commented [A9]: It's not the condition of use that's the limit on the presumption of disclosure, is the fact that it's manufacture for export. Leave the original language as is.

less the Administrator makes the determination in section 12(a)(2).

"(iii) PARTIAL BANS AND PHASE-OUTS.—In the case of a chemical substance or mixture for which the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to a specific condition of use of the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to the condition of use of the chemical substance or mixture for which the ban or phase-out is established.

Commented [A10]: How is this a "limitation" on A? This is exactly the situation that A seems to address.

"(C) REQUEST FOR NONDISCLOSURE.—

"(i) IN GENERAL.—A manufacturer or processor of a chemical substance or mixture subject to a ban or phase-out described in this paragraph may submit to the Administrator, within 30 days of receiving a notification under subsection (g)(2)(A), a request, including documentation supporting such request, that some or all of the information to which the notice applies should not be disclosed or that its

disclosure should be delayed, and the Administrator shall review the requestunder subsection (g)(1)(E).

"(ii) EFFECT OF NO REQUEST OR DENIAL.—If no request for nondisclosure or delay is submitted to the Administrator under this subparagraph, or the Administrator denies such a request under subsection (g)(1)(A), the Administrator shall promptly make the information public.

"(5) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information ø*reported to or otherwise obtained by the Administrator under this ƒAct / title*≈¿ that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(c) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect from disclosure any information that person submits under this øAct / *title?*¿ (including information described in paragraph (2))

shall assert to the Administrator a claim for protection from disclosure concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this øtitleé.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) ADDITIONAL REQUIREMENTS FOR CLAIMS REGARDING CHEMICAL IDENTITY IN-

FORMATION.—In the case of a claim under subparagraph (A) for protection from disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—

"(i) øbe consistent with guidance¿ ø*see questions below regarding guidance*¿ issued by the Administrator under paragraph (4)(A); and

"(ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are claimed as confidential; and

"(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

"(2) INFORMATION GENERALLY NOT SUBJECT TO SUBSTANTIATION REQUIREMENTS.—The following informationø, *as identified by the Administrator,?*¿ ø*this would clarify that the Administrator*

could ask for information if needed to prove that something falls into one of these categories, as discussed. shall not be subject to substantiation requirements under paragraph (3):

"(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(B) Marketing and sales information.

"(C) Information identifying a supplier or customer.

"(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

"(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

"(F) Specific production or import volumes of the manufacturer.

"(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify

Commented [A11]: The addition of "as identified by the Administrator" would likely significantly add to the transaction costs of operating under this paragraph, since the paragraph would apply to any piece of information only after the Administrator has "identified" it (not sure what that means, but it apparently is a step that would have to happen).

the specific chemical substance, if the specific identity was claimed as confidential at the time it was submitted in a notice under section 5.

"(3) SUBSTANTIATION REQUIREMENTS.—Except for information described in paragraph (2), a person asserting a claim to protect information from disclosure under this section øshall substantiate the claim, in accordance with rules promulgated, and consistent with guidance developed,¿ *øthis seems weird from an APA perspective - if a person is statutorily required to follow the guidance, it would probably end up being treated the same as a rule from a procedural standpoint, so to the extent that letting the Administrator do some things through guidance instead of a rule is intended to obviate the need for full rulemaking procedures, this might negate that. if that is a problem, might be better to say something more general here, like 'shall substantiate the claim in accordance with such requirements as the Administrator may establish'¿* by the Administrator.

"(4) GUIDANCE.—The Administrator shall develop øguidance¿ *øso, just checking, is this intended to be true guidance, or is it meant to be required to be followed? (1)(C) and (d)(4), (5), and (6) make it sound like they are requirements¿* regarding—

Commented [A12]: EPA has similarly commented that the Senate bill in certain respects treats guidance as rules. However, we believe we would have credible arguments to develop such guidance without notice and comment rulemaking.

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection from disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (d).

"(5) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B), and any information required to substantiate a claim submitted pursuant to paragraph (3), are true and correct.

"(d) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in subsection (a)—

"(1) shall be disclosed to an officer or employee of the United States—

"(A) in connection with the official duties of that person under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed to a contractor of the United States and employees of that contractor if—

Commented [A13]: Needs to be dropped

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines, without consideration of costs or other non-risk factors, that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use;

"(4) shall be disclosed to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law, if such entity has 1 or more applicable agreements with the Administrator that are consistent with the øguidance¿ developed under subsection (c)(4)(B) and ensure that the entity will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the proce-

dures used by the Administrator to safeguard the information;

"(5) shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement are consistent with the øguidance¿ developed under subsection (c)(4)(B);

"(B) the statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure

to the chemical substance or mixture concerned has occurred; and

"(C) the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information, øexcept that nothing in this title prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State lawż *øthis is a pretty broad statement. why is it being placed here, and not somewhere more general in the section?*ż;

"(6) shall be disclosed in the event of an emergency, to a treating physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police offi-

cer, firefighter, or emergency medical technician) if such person requests the information, subject to the conditions that such person shall—

"(A) have a reasonable basis to suspect that—

"(i) a medical, public health, or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred;

Commented [A14]: Seems like there be an "and" to link A and B.

"(B) if requested by a person who has a claim with respect to the information under this section—

"(i) provide a written statement of need and agree to sign a confidentiality agreement, as described in paragraph (5); and

"(ii) submit ø*to the person who has the claim? or to the Administrator? or both?*¿

such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the ømaximum¿ extent practicable without impairing the proceeding; øor / *and*¿

"(8) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(e) DURATION OF PROTECTION FROM DISCLOSURE.—

"(1) IN GENERAL.—Subject to paragraph (2), the Administrator shall protect from disclosure information described in subsection (a)—

"(A) in the case of information described in subsection (c)(2), until such time as—

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the

Commented [A15]: The addition of this, and the attempt to keep referencing para 2 in 1, is unnecessary and confusing, as reflected in the italicized questions below. 2 operates on its own.

Commented [A16]: This absolute command to protect information described in (a) creates issues, since it does not account for the information required to be disclosed under b. This is in line with the comment above – it suggests that (a) information is always witholdable, which would be a significant change in operation of sec 14.

Administrator shall promptly make the information available to the public; or

"(ii) the Administrator øbecomes aware that the information does not qualify for protection from disclosure under this section¿ *øwould this have to go through the review process in paragraph (2) first?¿*, in which case the Administrator shall take any actions required under subsection (f); and ø*should this instead be that the Administrator reviews the claim under (2) and decides it no longer qualifies? if not, how does a review there interact with this?¿*

"(B) in the case of information other than information described in subsection (c)(2)—

"(i) for a period of 10 years ø*from the date on which—¿*

"(I) ø*the person submits the information to the Administrator; or¿*

"(II) ø*the Administrator makes a determination that the claim continues to meet the relevant requirements of this section after requiring a person to*

Commented [A17]: Our understanding is that this is a review that can happen before the period specified in paragraph (2). Para (2) is completely separate.

Commented [A18]: Same comment. This is not a part of review under (2). 2 is solely for extensions to the period.

Commented [A19]: Again, (II) would be very confusing. We have read this as meaning (I) (and don't think it's necessary to say that, although that would probably be harmless).

reassert and substantiate or resubstantiate a claim under paragraph (2)¿; or

"(ii) if applicable before the expiration of such 10-year period or any extension granted under subparagraph (B), until such time as—

"(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(II) the Administrator øbecomes aware that the information does not qualify for protection from disclosure under this section¿, in which case the Administrator shall take any actions required under subsection (g). *øas above regarding interaction with paragraph (2)¿*

"(2) EXTENSIONS.—

"(A) IN GENERAL.—In the case of information other than information described in subsection (c)(2), not later than the date that is 60 days before the expiration of the period de-

Commented [A20]: Why add this? "Applicable" to what? Isn't it enough to just say it's protected for 10 years unless I or II occur?

Commented [A21]: Recommend not adding

Commented [A22]: This is completely unnecessary – the period described in paragraph 1B already excludes c2 information. Trying to say things multiple times creates confusion.

scribed in paragraph (1)(B), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(B) REQUEST.—

"(i) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in paragraph (1)(B), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (c)(3), the need to extend the period.

"(ii) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in paragraph (1)(B), the Administrator shall, in accordance with subsection (g)(1)—

"(I) review the request submitted under clause (i);

"(II) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant requirements of this section; and

"(III)(aa) grant an extension of 10 years; or

"(bb) deny the request.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under this paragraph, if the Administrator determines that the relevant request under subparagraph (B)(i)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(f) REVIEW AND RESUBSTANTIATION.—

"(1) DISCRETION OF ADMINISTRATOR.—The Administrator may requireø, under this subsection,¿ ø*what does this add? okay to strike?*¿ any person that has claimed protection for information from disclosure under this section, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to reassert and substantiate or resubstantiate the claim in accordance with subsection (c)—

"(A) after the chemical substance is ødesignated as a high-priority substance under section 6(b)¿ ø*need to check this reference*¿;

Commented [A23]: I agree that "under this subsection" does not add anything, and may be stricken without adverse impact.

"(B) for any øchemical substance designated as an inactive substance under section 8(b)(4)(A)(iii)¿ ø*need to check this reference*¿;

Commented [A24]: Wrong. The point of this is to allow review of inactive substances upon designation as active.

or

"(C) if the Administrator determines that disclosure of certain information currently protected from disclosure would be important to assist the Administrator in conducting risk evaluations or promulgating rules under section 6.

"(2) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information from disclosure under this section and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to reassert and substantiate or resubstantiate the claim in accordance with this section—

"(A) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(B) if the Administrator has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section; or

"(C) for any chemical substance the Administrator determines in accordance with section ø6(b)(4)(A)¿ ø*need to check this reference*¿ presents an unreasonable risk of injury to health or the environment.

ø"(3) PERIOD OF PROTECTION.—If the Administrator requires a person to reassert and substantiate or resubstantiate a claim under this paragraph, and determines that the claim continues to meet the relevant requirements of this section, the Administrator shall protect the information subject to the claim from disclosure for a period of 10 years from the date of such determination, subject to any subsequent requirement by the Administrator under this paragraph. ø*depending on answers in (1)(A), this may be entirely taken care of there. if so, strike this subparagraph.*¿¿

"(g) DUTIES OF ADMINISTRATOR.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except for claims regarding information described in subsection

Commented [A25]: The context is different. This provision applies once the administrator has issued an initial determination as necessary and 10 year period has already passed. The other applies to the first time a determination is made or information is submitted. Again, we find the effort to somehow link 1 and 2 confusing and unnecessary. They deal with different issues, and 2 can only be read to allow extension of the applicable period under 1.

(c)(2), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (c), and not later than 30 days after the receipt of a request for extension of a claim under subsection (e) or a request under subsection (b)(4)(D), review and approve, approve in part and deny in part, or deny the claim or request. *øgiven what's in (C) and (D), what does this subparagraph actually do?¿*

"(B) REASONS FOR DENIAL.—If the Administrator denies or denies in part a claim or request under subparagraph (A) the Administrator shall provide to the person that asserted the claim or submitted the request a written statement of the reasons for the denial or denial in part of the claim or request.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (c)(2)(G), review all claims or requests under this section for the protection from disclosure of the specific identity of a chemical substance; and

Commented [A26]: We don't see any problem with this provision, but (C) could be modified to state be general rule (including the 90-day timeframe) and (A) could be dropped.

"(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection from disclosure under this section.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection from disclosure or extension under this section shall not have the effect of denying or eliminating a claim or request for protection from disclosure.

"(E) DETERMINATION OF REQUESTS UNDER SUBSECTION (b)(4)(C).—With respect to a request submitted under subsection (b)(4)(C), the Administrator shall, with the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the ømaximumć extent practicable, determine whether the documentation provided by the person rebuts what shall be the presumption of the Administrator that the public interest in the disclosure of the information outweighs the public or proprietary interest in maintaining the protection for all or a portion of the information that the person has re-

quested not be disclosed or for which disclosure be delayed.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (b), (d), and (e), if the Administrator denies or denies in part a claim or request under paragraph (1), concludes, in accordance with this section, that the information does not qualify øor no longer qualifies¿ *øredundant. okay to strike?¿* for protection from disclosure, intends to disclose information pursuant to subsection (d), or promulgates a rule under section 6(a) establishing a ban or phase-out with respect to a chemical substance or mixture, the Administrator shall notify, in writing, the person that asserted the claim or submitted the request of the intent of the Administrator to disclose the information. The notice shall be furnished by øcertified mail (return receipt requested), by personal delivery, or by any other / *any?¿* means that allows verification of the fact and date of receipt.

"(B) DISCLOSURE OF INFORMATION.—Except as provided in subparagraph (C), the Administrator shall not disclose information under

Commented [A27]: I agree that "or no longer qualifies" is unnecessary and could be stricken without adverse impact.

Commented [A28]: Certified mail is intended to allow verification of the fact and data receipt, so is personal delivery of its done right. So I think "any other" is better, but either one would work.

this subsection until the date that is 30 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A).

"(C) EXCEPTIONS.—

"(i) FIFTEEN DAY NOTIFICATION.—For information the Administrator intends to disclose under subsections (d)(3), (d)(4), (d)(5), and (i), the Administrator shall not disclose the information until the date that is 15 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A), except that, with respect to information to be disclosed under subsection (d)(3), the Administrator determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information the Administrator intends to disclose under paragraph (6) of subsection (e), the Administrator

shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d); or

"(II) for the disclosure of information for which—

"(aa) the Administrator has provided to the person that asserted the claim a notice under subsection (e)(2)(A); and

"(bb) such person does not submit to the Administrator a request under subsection (e)(2)(B) on or before the deadline established in subsection (e)(2)(B)(i).

"(D) APPEALS.—

"(i) ACTION TO RESTRAIN DISCLOSURE.—If a person receives a notification under this paragraph and believes the information is protected from disclosure

under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C), the person may bring an action to restrain disclosure of the information in—

"(I) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(II) the United States District Court for the District of Columbia.

"(ii) NO DISCLOSURE.—

"(I) IN GENERAL.—The Administrator shall not disclose any information that is the subject of an appeal under this paragraph before the date on which the applicable court rules on an action under clause (i).

"(II) EXCEPTION.—Subclause (I) shall not apply to disclosure of information described under subsections (d)(4) and (i).

"(3) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention,

Commented [A29]: Note that this, read literally, prevents any disclosure of the information pending appeal, even if the disclosure is not related to the appeal. For example, if EPA provides notice of intent to release information because EPA has found it does not qualify for protection or because EPA has denied the claim, this provision would prevent EPA from releasing the information to a contractor during the appeal. We assume that was not the intent. That broad reading could be corrected by rewording (I) as follows: "If an appeal is filed under this paragraph, the Administrator shall not carry out the disclosure of information as described in the notification under this paragraph before the date on which the applicable court rules on the action under clause (i)". [Note that this comment applies to the Senate provision as well; this is not an issue created by HLC.]

shall develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).

"(4) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on the

list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section—

"(i) øis made public; and¿ *øthis seems to contradict the policy described in the meeting that not all nonconfidential information needs to affirmatively be made public. how does this subparagraph fit in to that policy?¿*

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the claim, and for which the Administrator has used a unique identifier assigned under this paragraph to identify the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the ømaximum¿ extent practicable.

"(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

Commented [A30]: To identify the chemical substance instead? Isn't the point not to identify the specific chemical identity?

"(1) INDIVIDUALS SUBJECT TO PENALTY.—

"(A) IN GENERAL.—Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be øguilty of a misdemeanor and¿ ø*Judiciary drafters suggest that this is unnecessary. strike?*¿ fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—An individual referred to in subparagraph (A) is an individual who—

"(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

"(ii) knowing that the information is protected from disclosure under this section, øwillfully¿ ø*Judiciary drafters note that this could be interpreted in this context as meaning either 'recklessly' or 'intentionally'. if there is a preferred policy, better to replace with one of those terms, otherwise can leave up to the courts*¿ discloses the information in any manner to any per-

son not entitled to receive that information.

"(C) EXCEPTION.—This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information *øobtained under paragraph (5) or (6) of subsection (d)¿* to øthe affected patient / *a patient treated by the medical professional¿ ø, or the legal representative of such a patient,?¿ øfor example, if the patient is a minor or incapacitated¿* as øpart of / *needed with respect to?¿* the diagnosis or treatment of the patient. *ømay the patient then disclose the information (for example, to another doctor for a second opinion or to a spouse)? if so, need to include the patient in this exception, along with any limitations desired¿*

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, or making known of information reported to or otherwise obtained by the Administrator under this Act. ø*Judiciary drafters note that it is unclear what this paragraph is intended to achieve¿*

"(i) APPLICABILITY.—

Commented [A31]: TSCA also includes "making available". Some reason that was stricken?

Commented [A32]: This is a key aspect of current TSCA. It is what makes exclusively TSCA, rather than the Trade Secrets Act, control the disclosure of confidential business information submitted under the act. The 1979 case of *Chrysler v Brown* held that the one enforces FOIA Exemption 4, which otherwise would be discretionary and the part of an agency. Without this provision, there would be a conflict of laws regarding information claimed as confidential and submitted to EPA under TSCA. This could be done in another way, but it's been in TSCA since 1976 and is well understood. Removing it from the statute at this point would give rise to an argument that Congress intended the Trade Secrets Act to apply to TSCA CBI. This would create unnecessary confusion.

"(1) IN GENERAL.—Except as otherwise provided in this section, øsection 8¿ ø*need to check this reference*¿, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or re-substantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator under this Act prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or re-substantiation requirements under this Act that are more extensive than those required under this section.

"(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or re-substantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century

Act. ø*this may be taken care of elsewhere in the bill. if so, strike here*¿

"(j) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 11:42:58 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal- Thank you for the catch. A parallel change should **also be made** to the "Prior-Initiated Evaluations." paragraph. Please let me know if any questions. Thanks,
Sven

On Apr 10, 2016, at 7:27 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just making 100% sure -- see my redlining p 22-23 of the HLC version.

ø(1) no changes to this para? PRIOR-INITIATED EVALUATIONS.—Nothing
14 in this Act, or the amendments made by this Act,
15 prevents the Administrator of the Environmental
16 Protection Agency from initiating a risk evaluation
17 regarding a chemical substance, or from continuing
18 or completing such risk evaluation, prior to the ef19
fective date of the policies, procedures, and guidance
20 required to be developed by the Administrator under
21 section 26(k) of the Toxic Substances Control Act,
22 as added by subsection (a) of this section.¿

ø(2) ACTIONS COMPLETED PRIOR TO COMPLE24
TION OF POLICIES, PROCEDURES, AND GUIDANCE.—
25 Nothing in this Act, or the amendments made by

April 8, 2016 (2:27 p.m.)
F:\KML\114\EC\TSCA\SEC26_01.XML
f:\VHLC\040816\040816.124.xml (626935|13)
23
[Discussion Draft]
1 this Act, requires the Administrator of the Environ2
mental Protection Agency to revise or withdraw a
3 completed risk evaluation, determination, or rule
4 under the Toxic Substances Control Act solely be5
cause the action was completed prior to the develop6
ment of a policy, procedure, or guidance under this section or section 6~~sec7~~
~~tion 26(k) of the Toxic Substances Control Act, as~~
~~8 added by subsection (a) of this section.¿~~

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey

255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 7:14 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the additional followup request on 6/26.

In response to your request for drafting assistance to ensure that all relevant guidance documents are included in the scope of the Section 26 provision, we suggest the following:

26(_) [Nothing requires EPA to revise or withdraw an action] . . . "solely because the action was completed prior to the development of a policy, procedure, or guidance under this section or under section 6."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** April 10, 2016 at 6:31:09 PM EDT
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: RE: Sen. Markey TSCA TA additional follow up on section 6/26**
>
> ok. thanks. so, given that, I'm planning to move 3. Into 26. The other 2 can't be addressed that way. using House text as your base, I think I need some drafting assistance. I'm afraid that sentence the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure." can't be included.
>
> Michal Ilana Freedhoff, Ph.D.
> Director of Oversight & Investigations
> Office of Senator Edward J. Markey
> 255 Dirksen Senate Office Building
> Washington, DC 20510
> 202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 4:21 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the followup request on 6/26.

We think there are 3 relevant requirements.

1. the requirement in 6b1 to establish by rule a risk-based screening process

2. the requirement in 6b4B to establish by rule the process for risk evaluations

3. The requirement in 6b4I to issue guidance as to how outside parties can submit their own draft risk evaluations

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 10, 2016 at 1:58:35 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA follow up on section 6/26
I understand. I am attaching the Senate's view of what section 6 looks like to resolve this concern for you. it has not yet been sent to the House despite its file name – I am hoping to resolve this section 26 issue before that occurs.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 5:13:02 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey Request on Revised section 14
Attachments: Comprehensive TA on Senate Sec 14 - March 16.docx; ATT00001.htm; 03-15-16PMTSCA - Bicam , EPA.docx; ATT00002.htm

Michal,
Attached is our TA on the new text you asked us to review. Also attached is our remaining TA on section 14, with respect to issues not affected by the new text. Note that we have added a couple of comments not in the last version of section 14 we sent you, which we have picked up on during this latest review.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 7:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 14

Sven

Thanks very much for all your rapid assistance today! Attached is a new draft of section 14. Not all changes have been agreed to among Senate offices – some are being discussed or proposed by us, some are raised by the House, etc. But this is at a stage where we would like EPA TA with an eye for concerns related to workability, possible unintended consequences, drafting concerns, inconsistencies, etc. Fast turnaround appreciated.

Thank you

michal

SEC. 14. CONFIDENTIAL INFORMATION~~DISCLOSURE OF DATA~~.

(a) IN GENERAL.—Except as otherwise provided in ~~by sub~~this section ~~(b)~~, the Administrator shall not disclose ~~any~~ information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

(1) that is reported to, or otherwise obtained by, the Administrator ~~(or any representative of the Administrator)~~ under this Act~~, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information —~~; and

(2) for which the requirements of subsection (d) are met.

(b) Information Generally Protected from Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(2) Marketing and sales information.

(3) Information identifying a supplier or customer.

(4) Details of the full composition of a mixture and the respective percentages of constituents.

(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

(6) Specific production or import volumes of the manufacturer.

(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

(8) ~~Except as otherwise provided in this section,~~ The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

(c) Information Not Protected From Disclosure.—

(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:

(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

(i) IN GENERAL.—Subject to clause (ii)—

(I) any health and safety study that is submitted under this Act with respect to—

(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

Commented [A1]: Obsolete citation. There are others in this section, which we have not marked.

Commented [A2]: Per TA provided on 3/15, this "subject to paragraph (2)" addition could give rise to issues, which would be significantly exacerbated by the proposed change to (2), per comments below.

(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or

(BB) a notification is required under section 5; or

(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(ii) A ~~safety assessment developed, or a safety determination made,~~ risk evaluation conducted under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with ~~or contained in~~ information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

(3) BAN OR PHASE-OUT.—(A) If the Administrator promulgates a rule pursuant to section 6(a3) that establishes a ban or phase-out of ~~the manufacture, processing, or distribution in commerce of~~ a chemical substance, ~~subject to paragraph (2), (3), and (4) of subsection (g),~~ disclosure of any information protection from disclosure ~~provided~~ under this section with respect to the ~~specific identity of the particular chemical substance and other information relating to the chemical substance shall no longer apply~~shall be presumed to be in the public interest, subject to a review of a request to maintain protections under subsections (g)(1), (g)(2) and (g)(3).

(BA) EXCEPTIONS FROM PRESUMPTION

(i) Paragraph (3)(A) shall not apply to if the chemical

Commented [A3]: This addition creates issues. Paragraph (1) identifies information that is not protected from disclosure. While such information can be *submitted with* protectable information, it is hard to see how it can *contain* protectable information. For example, (1)(A) provides, with certain limitations, that health and safety studies are not protected from disclosure. In general, information contained in a health and safety study would be *part of* the health and safety study. If the new language is read to say that any information in a health and safety study that would otherwise be protectable under section 14 remains protected, then that would drain (1)(A) of any force, since the point of (1)(A) (and to some extent the items in(1) (B)) is to require release of information that would otherwise be protectable.

Commented [A4]: This will not provide for release of the information, because nothing in the bill as revised authorizes EPA to release CBI on the grounds that EPA believes the release is in the public interest. In contrast, S 697 provided that protection "shall no longer apply".

substance or particulars conditions of use of thea chemicals substance asefor which an exemption under section 6(g) has been granted exempted from regulation under 6(g).

(ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established if the chemical substance is banned or phased out only for particular uses, the presumption shall only apply to claims solely related to the specific uses subject to the ban or phase out;

(iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured solely for export, consistent with section 12; and

(iv) Paragraph (3)(A) shall apply to for a chemical substance that is subject to a phase out at such time as the , the presumption shall not apply until such time as the phase out is fully implemented.

(3)(4) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is subject to disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

(d) Requirements for Confidentiality Claims.—

(1) ASSERTION OF CLAIMS.—

(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

(i) be consistent with guidance issued by the Administrator under paragraph (3)(A); and

(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

(I) that are considered to be confidential; and

Commented [A5]: This could be read to void the presumption for any information related to the chemical if an exemption is granted for any uses.

Commented [A6]: We are not sure what this would do, but it is confusing. It appears to just say that section 12 (12(a), presumably) governs, which is unnecessary because it governs on its own terms. Also, section 12(a) refers to manufacturing, processing and distribution. Is there a reason this provision applies only to manufacture?

(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and consistent with the guidance issued by the Administrator.

(3) GUIDANCE.—The Administrator shall develop guidance regarding—

(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are true and correct.

(e) Exceptions to Protection from Disclosure. ~~—Information~~ Notwithstanding paragraph (g)(3)(B) of this section, information described in subsection (a)—

(1) shall be disclosed ~~if the information is to shall be disclosed~~ to an ~~any~~ officer or employee of the United States—

(A) in connection with the official duties of that person—

(A) ~~such officer or employee~~ under any law for the protection of human health or the environment;, or

(B)

(B) for a specific law enforcement purposes;

(2) shall be disclosed ~~if the information is to shall be disclosed~~ to a contractors ~~of with~~ the United States and employees of that ~~such~~ contractors if—

(A) if, in the opinion of the Administrator, the ~~such~~ disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States ~~entered into on or after the date of enactment of this Act~~ for the performance of work in connection with this Act; and

(B) subject to ~~under~~ such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines that disclosure ~~it~~ is necessary to protect health or the ~~environmenenvironment~~ against an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors~~against an unreasonable risk of injury to health or the environment~~;

(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State or tribal government, on written request, for the purpose of development, administration, or enforcement of a law, if 1 or more applicable agreements with the Administrator that are consistent with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the

Commented [A7]: Why added here? TSCA generally refers to health, not human health. Compare (e)(3) below, which just uses "health".

Administrator to safeguard the information and penalties comparable to those under this Act for wrongful disclosure of the information;

Commented [A8]: This added language does not work grammatically

(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

(A) the statement of need and confidentiality agreement are consistent with the guidance issued under subsection (d)(3)(B);

(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

(i) the information is necessary for, or will assist in

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

(i) a medical or public health or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

(i) provide a written statement of need; and

(ii) agree to sign a confidentiality agreement; and

(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

(74) may be disclosed if the Administrator determines that disclosure is relevant ~~may be disclosed when relevant~~ in ~~any~~ a proceeding under this Act, subject to the condition ~~except~~ that the

disclosure is ~~in such a proceeding shall be~~ made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding.;

(8) ~~Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee shall be disclosed if the information is to be disclosed, on written request of any duly authorized committee of the Congress, to that committee;~~ or

(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

~~In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.~~

(f) Duration of Protection from Disclosure—

(1) IN GENERAL.—

~~(A) DURATION OF PROTECTION FROM DISCLOSURE INFORMATION NOT SUBJECT TO TIME LIMIT FOR~~

~~(B)~~(A) PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), ~~T~~the Administrator shall protect from disclosure.

(i) information described in subsection (b) that meets the requirements of subsections (a) and (d); ~~, and~~

~~(ii) for a period of 10 years, information other than information described in subsection(b) that meets the requirements of subsections(a) and (d) unless—~~,

unless

(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

~~(II)~~(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)~~(2)~~.

~~(C) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—~~

~~(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or~~

~~(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).~~

~~(D)~~(B) EXTENSIONS.—

(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (B), the Administrator shall provide to the person that asserted

Commented [A9]: The addition of this intro language, for (e)(8) only, may cause confusion, or generate arguments that the release standard for the other 8 items in (e) is more demanding than for this item. We recognize that this language is in TSCA currently only for Congressional release, but that appears to because Congressional release is addressed by its own subsection (14(e)), rather than in 14(a) where the other categories of releasable information are addressed; it therefore arguably needed the "Notwithstanding" language.

Commented [A10]: Per our 3/15 TA, the deletion of this language could create arguments that information that is subject to release under section 14 is nonetheless protectable under FOIA, which could largely drain the section 14 release provisions of any force.

Formatted: No underline, Underline color: Auto, Font color: Auto

Formatted: Indent: Before: 1.31", No bullets or numbering

Commented [A11]: Number is off. This is the second (i).

the claim a notice of the impending expiration of the period.

(ii) STATEMENT.—

(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (d)(2), the need to extend the period.

(II) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—

(aa) review the request submitted under subclause (I);

(bb) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant criteria established under this section; and

(cc)(AA) grant an extension of 10 years; or

(BB) deny the request.

~~(I)~~(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (C), if the Administrator determines that the relevant request under subparagraph (C)(ii)(I)—

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

(2) REVIEW AND RESUBSTANTIATION.—

(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection of information against disclosure under subsection (a) and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

(i) after the chemical substance is identified as a high-priority substance under section 6(b);

(ii) for any chemical substance the Administrator determines in accordance with subsection (b)(4)(A) presents an unreasonable risk of injury to health or the environment for which the Administrator has made a determination under section 6(c)(1)(C);

(iii) for any inactive chemical substance identified under section 8(b)(5)(B); or

(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations risk evaluations under section 6(b) subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(a).

(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information against disclosure under subsection (a) and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

Commented [A12]: Needs to add 6 (6(b)(4)(A))

Commented [A13]: Should retain "conducting"

(i) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5, United States Code;

(ii) if the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a); or

(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

(i) reassert and substantiate or resubstantiate the claim; or

(ii) withdraw the claim.

(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

(3) UNIQUE IDENTIFIER.—The Administrator shall—

(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

(i) is made public; and

(ii) identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

(g) Duties of Administrator.—

(1) DETERMINATION.—

(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), or receipt of a request to maintain protection of information subject to (e)(3), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, approve in part, or deny the claim or request.

(B) REASONS FOR DENIAL.—If the Administrator denies or denies in part a claim or request under subparagraph (A), the Administrator shall provide to the person that submitted the claim or request a written statement of the reasons for the denial or denial in part of the claim or request.

(C) SUBSETS.— The Administrator shall—

(i) except for claims described in subsection (b)(8), review all claims or requests under this section for the protection against disclosure of the specific identity of a chemical substance; and

(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection against disclosure.

(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim or request for protection against disclosure.

(2) NOTIFICATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e) and (f), if the Administrator denies or denies in part a claim or request under paragraph (1), intends to release information pursuant to subsection (e), or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

(B) RELEASE OF INFORMATION.—Except as provided in subparagraph (C), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

(C) EXCEPTIONS.—

(i) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim or request receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

(I) for the disclosure of information under paragraph (1), (2), (7), or (9) of subsection (e); or

(II) for the disclosure of information for which—

(aa) a notice under subsection (f)(1)(C)(i) was received; and

(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

~~(3) REBUTTABLE PRESUMPTION.—~~

~~(A) IN GENERAL.—With respect to notifications provided by the Administrator under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or a phase-out of the manufacture, processing, or distribution in commerce of the substance, as described in subsection (e)(3), there shall be a~~

rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released pursuant to paragraph (2)(B), a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

(C) DETERMINATION BY ADMINISTRATOR.—

(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A) for all or a portion of the information that the person has requested not be disclosed

~~OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.~~

~~(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.~~

~~(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released pursuant to paragraph (2)(B), a request pursuant to subparagraph (D), the Administrator shall promptly make public all of the information.~~

~~(4)~~(3) APPEALS.—

(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released pursuant to paragraph (2)(B), the person may bring an action to restrain disclosure of the information in—

(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

(ii) the United States District Court for the District of Columbia.

(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

~~(5)~~(4) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.

(h~~d~~) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

(A~~1~~) IN GENERAL.—Subject to paragraph (2), ~~Any~~ a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both. ~~or former officer or employee of the United States, who~~

(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

(I) by virtue of that ~~such~~ employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and

(B) ~~who~~ knowing that disclosure of that ~~such~~ material is prohibited by ~~such~~ subsection (a), willfully disclos~~ur~~es the material in any manner to any person not entitled to receive that material~~it~~,

~~shall be guilty of a misdemeanor and fined not more than $5,000 or imprisoned for not more than one year, or both.~~.

(2) OTHER LAWS.—Section 1905 of title 18, United States Code, ~~does~~ shall not apply with respect to the publishing, divulging, disclosure, ~~or~~ making known of, or making available, information reported or otherwise obtained under this Act.

(3~~2~~) CONTRACTORS.—For the purposes of this subsection~~paragraph (1)~~, any contractor with the United States that ~~who~~ is provided ~~furnished~~ information in accordance with ~~as authorized by~~ subsection (e~~a~~)(2), including ~~and~~ any employee of that ~~any such~~ contractor, shall be considered to be an employee of the United States.

(i) APPLICABILITY.—

(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable federal law, the Administrator shall have no authority—

(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, approving in part or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

~~(b) DATA FROM HEALTH AND SAFETY STUDIES.—(1) Subsection (a) does not prohibit the disclosure of—~~

~~(A) any health and safety study which is submitted under this Act with respect to—~~

~~(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or~~

~~(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and~~

~~(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).~~

~~This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.~~

~~(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the~~

Commented [A14]: We don't see the inconsistency and note that this provision is in current TSCA. Without this, arguments may be raised that section 1905 provides for broader protection than section 14. Because this provision has been in TSCA from its inception, removing the provision would create confusion as to the applicability of section 14 vs. the Trade Secrets Act.

Commented [A15]: Previously, "under this Act" appeared after "Administrator". Why removed? The revised version bars substantiation for information received under other EPA statutes.

Administrator may not deny such request on the basis of subsection (b)(4) of such section.

(e) DESIGNATION AND RELEASE OF CONFIDENTIAL DATA.—(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.

(2)(A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce submitting such data has received the notice required by this subparagraph.

(B)(i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in the second sentence of such subsection.

(e) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~**.**

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g)~~.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

Commented [A1]: As we have previously pointed out, the reference to subsection (a) appears to make (b) completely inoperative. It says that the listed items are generally CBI, but only to the extent that they would be CBI under ordinary FOIA law – a finding EPA would presumably have to make before (b) is triggered. What does this paragraph add to ordinary FOIA law? In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A2]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under section 6.

Commented [A3]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

"~~(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"~~(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"~~(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"~~(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** **4** "~~(2)~~**"(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the

performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency

medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or no longer qualifies for protection against disclosure under subsection (a)**, in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required**

under subsection (g)(2).

"(B) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—**Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)—**

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to

a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

Commented [A4]: This may be very difficult to do logistically. Note that the provision is not limited to information received under TSCA. Consider adding "to the extent feasible".

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

Commented [A5]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A6]: Certified mail is a cumbersome form of notification.

"(B) RELEASE OF INFORMATION.—**Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator

~~pursuant to subsection (c)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL~~

Commented [A7]: Note that this provision applies to information released under (e), as well as information released based on an EPA determination that it is not CBI. Thus, release to first responders, Congress, etc., can be held up by the filing of an appeal. Is that intended? If not, this could be addressed in various ways (e.g., by adding in the intro to (e) "Notwithstanding paragraph (g)(3)(B) of this section. . . ."

~~USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims

Commented [A8]: This provision is confusing. The "information" in question would already have been submitted to EPA, so how would EPA be able to determine the format and language of the information? Also, subsection (g) already provides the timeframes for release of the info, so what more would EPA do to allow for expedient and swift access?

as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/23/2016 12:56:21 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on 6(a) alternatives

Michal, we took a closer look at the section 6(a) alternatives on which you requested TA on March 22 and have some reactions and also some proposed alternative language.

First, we were concerned that the way in which that language regarding cost was inserted created uncertainties regarding the role of cost. It might have been argued that the language suggested that the unreasonable risk that had to be eliminated was one in which cost played a role.

In addition, the reference to cost and other non-risk factors could appear to suggest that they were more important than the other factors listed in subsection (c)(2).

The alternative language below splits 6(a) into two sentences. The first establishes the principle that cost and other non-risk factors do not play a role in determining whether a chemical substance presents an unreasonable risk and in setting the objective or goal for the risk management actions. To reinforce this we refer to subsection (b)(4)(A) explicitly in connection with the objective as well as the initial assessment of the chemical substance.

The second sentence addresses the selection of the particular risk management requirement or requirements and states that the choice is to be made taking into consideration costs and other factors in accordance with subsection (c)(2) (i.e., it highlights the term costs but the reference includes all the factors listed in (c)(2)).

This language could be used as a stand-alone option or could be combined with the other language we previously suggested to refer to cost-effectiveness in (c)(2).

SCOPE OF REGULATION—If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, then the Administrator shall by rule, and subject to section 18, apply one or more of the following requirements to such substance or mixture to the extent necessary [to ensure/so] that the chemical substance does not present such unreasonable risk, as determined in accordance with subsection (b)(4)(A), under the intended conditions of use. In selecting the particular requirement or requirements to be applied pursuant to this subsection, the Administrator shall, inaccordance with subsection (c)(2), take into consideration costs and other factors in choosing among the requirements evaluated.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/1/2016 11:34:42 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: TSCA TA on section 14 TA
Attachments: 14-03-31-16cleanedupTOEPA-simple markup-through c3 (1).docx; ATT00001.htm

Michal,
TA on section 14. Thanks,
Sven

Here are our overarching comments on the CBI section through 14(c). We have not yet done a detailed review of the remainder of the section.

SEC. 14. CONFIDENTIAL INFORMATION~~DISCLOSURE OF DATA~~.

~~x-refs not all conformed pending review of text~~

(a) IN GENERAL.—Except as ~~otherwise~~ provided in ~~by sub~~this section ~~(b)~~, the Administrator shall not disclose ~~any~~ information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

(1) that is reported to, or otherwise obtained by, the Administrator ~~(or any representative of the Administrator)~~ under this Act~~, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information~~—; and

(2) for which the requirements of subsection (d) are met.

(b) Information ~~Generally~~ Protected from Disclosure and ~~Generally~~ Not Subject to Substantiation.—Nothing in this section prohibits the protection from disclosure of ~~T~~the following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) ~~shall be presumed to be protected from disclosure~~, subject to the condition that nothing in this Act prohibits the disclosure of any ~~such~~ information~~, or information that is the subject of subsection (c)(3)~~, through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(2) Marketing and sales information.

(3) Information identifying a supplier or customer.

(4) Details of the full composition of a mixture and the respective percentages of constituents.

(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

(6) Specific production or import volumes of the manufacturer.

(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

(8) ~~Except as otherwise provided in this section, t~~The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

(c) Information Not Protected From Disclosure.—

~~(1) IN GENERAL.—Notwithstanding s~~Subsections (a) ~~and (b), and subject to paragraph (2), do not prohibit the disclosure of the following information shall not be protected from disclosure:~~

~~(2)~~(1) DATA FROM HEALTH AND SAFETY STUDIES.— Subsections (a) and (b) do not prohibit the disclosure of

(A) any health and safety study which is submitted under this Act with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

Commented [BD1]: The title doesn't match what this text is actually doing. There's nothing in the text of this subsection that talks about substantiation.

Commented [A2]: Based on yesterday's conversation, we had understood that (b) would provide that nothing in *subsection (a)* prohibits the protection from disclosure of the (b) information. This, instead, seems to provide for protectability for all of this information, even if in a health and safety study (since (c) is part of this section). Confusingly, 14(c) now provides that it operates notwithstanding (b). So, each one purports to trump the other.

Commented [A3]: QUESTION TO EPA: This change was made in order to mirror the change in 14(c)(1) which reverts the health and safety info language back to existing TSCA. We note there could be conflicts between this text and other subsections (including but not limited to 14(c)), even though the EPA notification/review process under 14(g) could also be argued to mitigate against that conflict. We'd appreciate your careful read and feedback.

Commented [A4]: Per earlier TA, the inclusion of (a) here seems to deprive (b) of any effect. If the (b) information must first be determined to satisfy (a) before it is protectible, then it's hard to see how (b) does anything, since any information that satisfies (a) and (d) is protectible.

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

~~(3)~~(2) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—Subsections (a) and (b) do not prohibit the disclosure of ~~The following information is not protected from disclosure under this section:~~

(A) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(B) A risk evaluation conducted under section 6.

(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~(4)~~(3) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section ~~this is not of the types of information described in (c)(1), (c)(2) or (c)(4),~~ and that is submitted with or contained in information described ~~(c)(1), (c)(2) or (c)(4) in this section~~, shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Formatted: Normal, No bullets or numbering

Formatted: Font: Times New Roman, 10 pt

Commented [u5]: Suggested revisions to prevent the otherwise available argument that (3) largely deprives (1), (2) and (4) of any effect.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 2:26:24 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Section 5 - early morning
Attachments: 5-04-05-16-EARLY AM TA.EPA TA.doc

Michal – TA responding to your comments on section 5 attached. EPA comments in blue. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 6:00 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Section 5

Sven - comments in yellow are for you, changes marked with blank comment boxes and a couple in green for Dimitri. Pls take one more FAST look, need to get this to the House asap.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.
Internal x-refs where existing TSCA lettering/numbering changed have not been conformed pending review of text

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsections (b), (e) or (f); and

(ii) the Administrator conducts a review of the notice and either

(I) ~~, makes a determination under paragraph (3)(A) or and, as necessary, issues an order to restrict such manufacturing or processing subsection (g), and, if necessary, under subsection (f)(1), takes applicable action required under subsection (f) or~~

(II) makes a determination under paragraph (3)(B) and ~~issues an order to prohibit or otherwise restrict such manufacturing or processing under subsection (e). any applicable action required under subsections (e) or (f).~~

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Before the end of the applicable period for review under paragraph (1), and ~~subject to section 18, the Administrator shall review a notice received under paragraph (1) and—~~

(A) determine whether ~~if~~ the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use., and take applicable action under subsection (f); or

(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (b)(3).

Commented [A1]: TO EPA: I didn't like required. It is never "required" for EPA to issue orders to allow manufacture under (e) or (f). EPA could just decide no restriction will fix the particular chemical. Tell me if you disagree or if you think "as necessary" is limiting.

Commented [A2R1]: EPA TA: We're ok with your wording, but (f) DOES by its terms require EPA to issue an order if EPA makes the may present finding, and "required" does seem more precise.

Commented [A3]: Michal agrees with EPA TA. (g) is what happens AFTER a determination and is not the actual determination. The determination in question is the one in paragraph 3(A) that is referenced here.

Commented [A4]: Michal switched these to read the same way. No need to have the word "prohibit" because if it is prohibited, the premise of this subsection makes no sense – manufacture IS prohibited unless these things occur, and no need for "necessary" in (II) because if a (B) determination is made the ONLY way manufacture can proceed is via an order.

Commented [A5]: Restored "whether" per EPA

(4) Failure to Render Determination.—

(A) In General.—The Administrator shall complete a review of a notice required by this section within the review period provided in subsections (a) and (c).

(B) Failure to Render Determination.—If the Administrator fails to make a determination on a notice under paragraph 3 or under subsection (g) by the end of the applicable review period, including an extension pursuant to subsection (c), the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make such determination.

(C) Limitations.—

(i) A refund of applicable fees under subparagraph (B) shall not be made if the Administrator certifies that the submitter has not provided information required under subsections (b) or (e) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review; and

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) SUBMISSION OF ~~TEST DATA~~INFORMATION.—

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit ~~test data~~information for such substance pursuant to a rule, order or consent agreement ~~promulgated~~ under section 4 before the submission of such notice, such person shall submit to the Administrator such ~~data~~ information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule or order ~~promulgated~~ under section 4 before the submission of such notice,

such person may not, before the expiration of the 90-day period which begins on the date of the submission in accordance with such rule or order of the ~~test data~~ information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2)(A) If a person—

Commented [A6]: Actually I think we DO want EPA to do SOMETHING before the first 90 days elapses under paragraph (3) above. We don't really want a 90 day extension to be made before EPA decides to order a test or ask for more information. I think these timeframes should not be consistent. Feel free to disagree, EPA.

Commented [A7R6]: EPA TA: Not sure we follow the logic of the different descriptions of review periods, and we don't see anything that requires EPA to order tests or ask for info within the 90 days. We have the impression you may be thinking that EPA must try to work out an agreed extension under (b) before it unilaterally extends under (c), but the bill does not require that and it would be contrary to current EPA practice.

Commented [A8]: Michal agrees that (g) is what happens AFTER a 3(A) determination that all is ok.

Commented [A9]: EPA TA: Seems unnecessary

Commented [A10]: EPA TA: How about: "and neither the Administrator nor the submitter shall be relieved of any requirements or restrictions under this section". Seems like the most important thing to clarify is not that EPA is not off the hook, but that manufacture can't proceed on the grounds that EPA is late.

Commented [A11]: This work?

Commented [A12]: Note to House: the way this was originally drafted in your Section 5 conforming changes, it allows manufacture 90 days after the date the information was required to be submitted, whether the information was submitted or not. Changed back to existing TSCA which keys off the date the information was actually submitted to EPA.

Commented [A13]:

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (5~~4~~), and

(ii) is not required by a rule, order, or consent agreement ~~promulgated~~ under section 4 before the submission of such notice to submit ~~test data~~information for such substance,

such person shall submit to the Administrator ~~data~~ information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) InformationData submitted pursuant to subparagraph (A) shall be information~~data~~ which the person submitting the ~~data~~ information believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) If the Administrator determines under subsection (a)(3)(B) that additional information is necessary to make the determination under subsection (a)(3)(A), the Administrator—

(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

(C) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information;

(D) on receipt of the additional information the Administrator finds supports the determination under subsection (a)(3)(A), shall promptly make the determination; and

(E) may take the actions specified in subsection (e).

(4~~3~~) ~~Data~~ Information submitted under paragraph (1), ~~or~~ (2) or (3) shall be made available, subject to section 14, for examination by interested persons.

(5~~4~~)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those

Commented [A14]: Note to House: per EPA, there could be other factors that go into an unreasonable risk finding and they suggest deleting the limitation on what they can consider, which is why we edited your Section 5 change here.

uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, ~~except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A)~~.

(c) EXTENSION OF NOTICE AND REVIEW PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may, subject to any necessary requirements under subsection (e) or (f), begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any ~~test data~~information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information~~data~~ concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information~~data~~ under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or information~~data~~ has been received;

(B) lists the conditions of use of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator s or intended uses of such substance; and

(C) in the case of the receipt of information ~~data~~ under subsection (b), describes the nature of the tests performed on such substance and any information ~~data~~ which was developed pursuant

Commented [A15]: EPA TA: Suggest changing "conditions of use" to "uses". "Conditions of use" is defined as including all reasonably foreseeable uses, so it is confusing to refer to intended uses as conditions of use.

Commented [A16]: Note to House- we think the 5 day timeframe is probably a tough timeframe for EPA to have to satisfy the full "conditions of use" definition which is why we have made this change.

to subsection (b) or a rule, order, or consent agreement under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the ~~notification~~ period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such ~~notification~~ period has expired since the last publication in the Federal Register of such list.

(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1)~~(A)~~ If the Administrator determines that—

~~(i)~~ the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) ~~permit a reasoned evaluation of the health and environmental effects of~~ for a chemical substance or significant new use with respect to which notice is required by subsection (a)~~, and~~

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance~~, the Administrator may issue ~~an proposed~~an order to take effect on the expiration of the applicable notification and review period ~~applicable to the manufacturing or processing of such substance~~ under subsection (a), (b), or (c)~~,~~ to prohibit or ~~or limit~~ otherwise ~~—~~restrict the manufacture, processing, distribution in commerce, use, or disposal of ~~such~~ the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or to prohibit or ~~limit~~ otherwise restrict any combination of such activities, sufficient ~~to~~ to enable the Administrator to conclude that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors. ~~to address the potential risk ofso that the chemical substance or significant new use until the Administrator makes the determination in~~ subsection (a)(3)(A).

(2B) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under ~~sub~~paragraph (1A), the Administrator shall consider costs and other non-risk factors.

(3C) If the Administrator issues an order under ~~sub~~paragraph (1A), n~~N~~o person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this paragraph except in compliance with the restrictions specified in the~~such an order issued under subparagraph (A)~~.

Commented [A17]: To EPA: I understand your consistency point. But EPA can extend the period under (b) or (c), and there is a required 90 days in (a). AFTER the process is completed, there is no longer a need to specify (b), ie in the 'failure to render' section, because it will have been subsumed by (c)

Commented [A18R17]: EPA TA: See above comment re deadlines and consistency

Commented [A19]: EPA: I agree that prohibit makes no sense if we are just talking about the "substance" in this subsection, but what if EPA decides to allow an industrial use and prohibit a consumer use while it waits for testing? I think prohibit should stay in both places it appears here. Feel free to argue with me.

Commented [A20]: EPA TA: We are ok with the language.

Commented [A21]: Per EPA – Dimitri, can we please leave it this way for now? 'Sufficient to address' is very vague. How about: 'sufficient to enable the Administrator to conclude, without consideration of costs or other non-risk factors, that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment'? As we indicated in prior TA, we think this stanard is entirely workable and understandable for judging the safety of a chemical with defined regulatory boundaries on use, even in scenarios where we don't know enough to make an affirmative statement about which side of the "may present an unreasonable risk" line the chemical would sit on if use is unregulated."

Commented [A22]: EPA TA: This looks like stray text

Commented [A23]:

Commented [A24]:

(4D) Not later than 90 days after issuing an order under ~~sub~~paragraph (1A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) A proposed order may not be issued under ~~sub~~paragraph (1A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

~~(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.~~

~~(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—~~

~~(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or~~

~~(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,~~

~~the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).~~

~~(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.~~

~~(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—~~

~~(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a), and~~

Commented [A25]: DIMITRI – per EPA : Why include this? This is designed in TSCA as a protection for the submitter against late hits from EPA, but in this bill, the submitter NEEDS this order to move ahead.

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment,~~ without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the ~~conditions of use, or~~

~~(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.~~

~~(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.~~

~~(D) After the submission to the Administrator of~~ information~~test~~ data ~~sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such information~~data by the Administrator, ~~the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.~~

(f) PROTECTION AGAINST ~~POTENTIAL~~ UNREASONABLE RISKS.—(1) If the Administrator ~~finds~~ determines that ~~there is a reasonable basis to conclude that~~ the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may ~~presents or will~~ present an unreasonable risk of injury to health or environment in accordance with subsection (a)(3)(A), ~~before a rule promulgated under section 6 can protect against such risk,~~

(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable notification and review period ~~applicable~~ under subsection (a), (b), or (c) ~~to the manufacturing or processing of such substance, or to the significant new use,~~ to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to enable the Administrator to conclude that the chemical substance or the significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk

Commented [A26]:

factors. ~~protect against such risk.—for the Administrator to determine that the chemical substance or significant new use is not likely to present such risk take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk~~.;

(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this subsection except in compliance with the restrictions specified in the order; and

(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(2) In selecting among prohibitions and other restrictions to include in a~~A~~n order to be issued by ~~T~~the Administrator to meet the standard under paragraph (1) of this subsection or under subsection (e)(1)(A) , the Administrator shall consider costs and other non-risk factors, and such an order may include~~issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—~~

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

~~Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.~~

(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A), reduce potential exposure to the substance to the maximum extent practicable.

(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

~~(3)(A) The Administrator may—~~

Commented [A27]: Dimitri – same as in (e). Can we keep this? EPA TA: Would be better to say "sufficient to enable the Administrator to conclude, without consideration of costs or other non-risk factors, that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment". Even with "such risk", "protect against" is vague. Although (e) and (f) have different on-ramps, conceptually it's hard to see why the objective of regulating would be different.

Commented [A28]: EPA TA: Should add a comma here

Commented [A29]:

Commented [A30]: To EPA: I am trying on your catch-all for 6 in the 6 mtgs we have had. Now that I see how you've been viewing our 6(a) list, once you're done with sections 4 and 5, can you please look at Senate offer 6 and tell me whether the "all uses" mini-catch-alls we stuck in are enough for you, and if not, what is still needed to address the concern? Also, I understand this list of requirements is stupidly drafted but every time we re-write parts of existing TSCA that substantively do not require re-writing we get yelled at, so…

Commented [A31R30]: EPA TA: The "all uses" catch-alls do not do the trick. In fact, they don't add any authority, because they just make 62A and B redundant of 6a1. What's missing is general authority to "otherwise regulate" manufacture, processing and distribution, and is provided for use in 6a5, and for disposal in 6a6.

The issue could be addressed by adding "or otherwise regulating" after the first "prohibiting" in section 6(a)(1)(A). If you do that, 6(a)(1)(B) and 6(a)(2) become superfluous and could be deleted. If that is too much change, than you could retain 6(a)(2)(A), adding "or otherwise regulating" after "prohibiting". If you make those changes, we suggest dropping 6(a)(1)(B) and 6(a)(2)(B), since those seem clearly subsumed by the general authority to regulate mfr, processing and distribution.

Commented [A32]: EPA TA: Should probably be "sufficient to enable the Administrator to conclude that"

~~(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or~~

~~(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.~~

~~(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use.~~

(g) STATEMENT ~~OF REASONS FOR NOT TAKING ACTION~~ ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not justified, then notwithstanding any remaining portion of the period for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of such substance or of such substance for a significant new use, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use, and ~~has not initiated any action under this section or section 6 or 7 to prohibit or limit the~~

Commented [A33]: Per EPA, they HAVE taken action under this re-written 5. This subsection is about them saying "all ok".

~~manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance,~~ the Administrator shall publish a statement of the Administrator's ~~determination~~finding reasons for not initiating ~~such action~~. Such a statement shall be ~~submitted for published~~ publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator for the specific uses identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information ~~data~~ for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

Commented [A34]: Leg counsel to conform internal X-refs here if needed

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information~~data~~ has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information~~data~~ by the applicant on such substance would be duplicative of information~~data~~ which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information ~~data~~ on such substance. No exemption which is granted under this subparagraph with respect to the submission of information~~data~~ for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information~~data~~.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information~~data~~ required under subsection (b)(2) for a chemical substance because of the existence of previously submitted ~~data~~information and if such exemption is granted during the reimbursement period for such information~~data~~, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the information~~data~~ on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such information ~~data~~, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information ~~data~~ for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such information~~data~~ to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such information~~data~~,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, ~~. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).~~ including an

unreasonable risk to a potentially exposed or susceptible population identified by the Administrator under the conditions of use.

(~~5~~4) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(~~6~~5) Immediately upon receipt of an application under paragraph (1) or (~~5~~4) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) DEFINITIONS.—

(1) For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(2) For purposes of this Act, the term 'requirement' as used in this section does notshall not displace any statutory or common law.

[15 U.S.C. 2604]

Commented [A35]:

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/28/2016 1:03:31 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on costs analysis
Attachments: Markey.TSCA TA.Costs Analysis.Senate Offer 4.24 - Section 5.docx; ATT00001.htm; Markey.TSCA TA.Costs Analysis.Senate Offer 4.24 - Section 5.docx; ATT00002.htm

Michal,
This TA responds to the request on cost considerations.

In particular, there are three comments to point out. The most important is the comment on p. 49 [44] of the second document (RLSO of HLC 4 22), which addresses the cost analysis issue for alternatives we have discussed.

The other two are on p. 137 [124] of that document (addressing discrepancies in the drafting of section 21) and p. 8 of the first document (suggesting text to align the sec 5 review period with the obligation to respond to information submitted).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 4:15:01 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: TSCA TA

Michal – 14 close – will be next

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 12:14 PM
To: 'Freedhoff, Michal (Markey)' <Michal_Freedhoff@markey.senate.gov>; 'Black, Jonathan (Tom Udall)' <Jonathan_Black@tomudall.senate.gov>; 'Deveny, Adrian (Merkley)' <Adrian_Deveny@merkley.senate.gov>
Subject: TSCA TA on HLC section 4 (4-18)

Michal, Jonathan and Adrian,
The attached TA responds to the request to compare section 4 - SLC and HLC (4-18) versions.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.
Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 11:28:53 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA additional follow up on section 6/26

Got it - checking

On Apr 10, 2016, at 7:27 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just making 100% sure – see my redlining p 22-23 of the HLC version.

ø(1) no changes to this para? PRIOR-INITIATED EVALUATIONS.—Nothing
14 in this Act, or the amendments made by this Act,
15 prevents the Administrator of the Environmental
16 Protection Agency from initiating a risk evaluation
17 regarding a chemical substance, or from continuing
18 or completing such risk evaluation, prior to the ef19
fective date of the policies, procedures, and guidance
20 required to be developed by the Administrator under
21 section 26(k) of the Toxic Substances Control Act,
22 as added by subsection (a) of this section.¿

ø(2) ACTIONS COMPLETED PRIOR TO COMPLE24
TION OF POLICIES, PROCEDURES, AND GUIDANCE.—
25 Nothing in this Act, or the amendments made by

April 8, 2016 (2:27 p.m.)
F:\KML\114\EC\TSCA\SEC26_01.XML
f:\VHLC\040816\040816.124.xml (626935|13)
23
[Discussion Draft]
1 this Act, requires the Administrator of the Environ2
mental Protection Agency to revise or withdraw a
3 completed risk evaluation, determination, or rule
4 under the Toxic Substances Control Act solely be5
cause the action was completed prior to the develop6
ment of a policy, procedure, or guidance under this section or section 6~~sec7~~
~~tion 26(k) of the Toxic Substances Control Act, as~~
~~8 added by subsection (a) of this section.¿~~

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 7:14 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the additional followup request on 6/26.

In response to your request for drafting assistance to ensure that all relevant guidance documents are included in the scope of the Section 26 provision, we suggest the following:

26(_) [Nothing requires EPA to revise or withdraw an action] . . . "solely because the action was completed prior to the development of a policy, procedure, or guidance under this section or under section 6."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** April 10, 2016 at 6:31:09 PM EDT
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: RE: Sen. Markey TSCA TA additional follow up on section 6/26**
>
> ok. thanks. so, given that, I'm planning to move 3. Into 26. The other 2 can't be addressed that way. using House text as your base, I think I need some drafting assistance. I'm afraid that sentence the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure." can't be included.
>
> Michal Ilana Freedhoff, Ph.D.
> Director of Oversight & Investigations
> Office of Senator Edward J. Markey
> 255 Dirksen Senate Office Building
> Washington, DC 20510
> 202-224-2742
>
> Connect with Senator Markey
> <image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 4:21 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the followup request on 6/26.

We think there are 3 relevant requirements.

1. the requirement in 6b1 to establish by rule a risk-based screening process

2. the requirement in 6b4B to establish by rule the process for risk evaluations

3. The requirement in 6b4I to issue guidance as to how outside parties can submit their own draft risk evaluations

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 10, 2016 at 1:58:35 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA follow up on section 6/26

I understand. I am attaching the Senate's view of what section 6 looks like to resolve this concern for you. it has not yet been sent to the House despite its file name – I am hoping to resolve this section 26 issue before that occurs.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 4:29:46 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on Animal testing

thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 12:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on Animal testing

Thanks - I don't know the answer to your related question butwill try to find out

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 12:26 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on Animal testing

Michal,
This TA responds to the request on animal testing language.

This language does not raise any drafting or policy issues for us.

We have a related question. Does this language address questions raised by Sen. Booker asking whether EPA has a concern that voluntary tests look to non-animal testing first and will lead to less information getting to EPA. Is the Booker issue about language that has been stricken?

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.

"(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule.

Keep tiered testing, but tweak it:

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.";

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 4:34:13 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Udall TSCA TA On Sec. 26

Jonathan,
we have no issues to flag on the sec 26 changes. Please let me know if any additional questions. Thanks,
Sven

Would like to check with you on the impact of making these changes to the Senate offer...

26(b)(4) do the following:

- Include such amounts as are deposited in the Fund under this paragraph with (4)(A)
- Strike (4)(A)(ii) and (iii)
- Strike (B)(ii)(III) [I know our intent it to section off TSCA money, but I'm not sure what it means]
- Strike (4)(C)
- Add House passed (b)(3)(e) "Accounting and Auditing"
- We have already taken their "Auditing" language and struck ours.
- They are keeping our "Termination" language

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 4:05:13 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on revised section 26 (WEI16263)

Michal,
This TA responds to the request on revised section 26.

Section 26 looks good.

Note that we've given further thought to our earlier TA that Section 26(b)(4)(D)(iii) would prevent EPA from collecting fees to defray the costs of risk management work flowing from an industry-requested risk evaluation. On further reflection, we believe it is reasonable to interpret this clause as only applying to the fee that EPA would collect from the requestor to cover the cost of the risk evaluation, so that it would not bar EPA from later assessing a follow-on fee (under 26(b)(1)(A)) to defray the costs of any necessary risk management rulemaking. You didn't make any changes in response to our earlier TA – we're just flagging our amended view on this point.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 15, 2016 at 6:35:31 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: revised section 26 (WEI16263)

Can you take a look? If ok, we can have slc conform the current hlc version of the same section. Sometime this AM good.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 10:46:04 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on section 8 nomenclature language

Michal - Got it, thanks. The (B)(i) reference is a placeholder. We have concerns that need further internal discussion. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 6:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Markey TSCA TA request on section 8 nomenclature language

Re statutory mixtures – does EPA currently have authority to designate new statutory mixtures? I think the intent of the language is to ensure that EPA could add new mixtures in the future and no intent to create the court argument you're fearing.

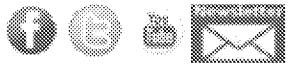
Also, are your concerns with (A)(iii) or (B)(i)? your email says the latter but your comments are on the former.

Monday shouldn't be a problem but the answer to the question on EPA authority with statutory mixtures would be helpful.

Thanks
m

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 6:02 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request on section 8 nomenclature language

Michal – while understanding the TA request's urgency, given schedules and the specific technical and legal knowledge required on nomenclature, we need to hold off responding fully until Monday. We have concerns about (B)(i) and need more time to articulate them. Please let me know right away if that is a problem.

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the TSCA inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include byproducts that do not appear on the TSCA inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

Response: Although not able to fully respond yet, we have several concerns, including that the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six, creating the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

Response: EPA has no concerns with the (B)(ii) language

We continue to work on this TA request, please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Sent: Monday, March 21, 2016 7:08 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: Time-sensitive on section 8

Sven

Can you pls rush the review of this redlined text to portions of section 8?

Here are the basic questions:

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the tsca inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include biproducts that do not appear on the tsca inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear

process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

I think there is a desire to get this to the House asap.

Thanks
M
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/16/2016 9:31:18 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Request - "unreasonable risk"

Michal – on rescheduling – Weds is not good for us, we can move the call up to 4 pm if that helps. We're also available at 11:30 on Thurs, just not 2-4. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 16, 2016 2:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Request - "unreasonable risk"

Should be ok

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, February 16, 2016 2:30 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Request - "unreasonable risk"

Michal – Jim has a 4pm, any chance we can push it to 4:30pm? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Tuesday, February 16, 2016 1:58 PM
To: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Re: Request - "unreasonable risk"

Michal - 4 pm on Thurs, Feb 18 works for us. Call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Thanks,
Sven

On Feb 16, 2016, at 12:47 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Call Thursday afternoon sometime btw 2-5?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, February 16, 2016 12:37 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Request - "unreasonable risk"

Michal – we're glad to provide TA in whatever way work best for you and your colleagues. What's your timeframe on getting folks together – I'll check on availabilities. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 16, 2016 12:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Request - "unreasonable risk"

Sven

There's an interest on the part of some (bipartisan) Senate staff to walk through (conference call is fine, so is mtg, so is you sending us a TA document - whatever is best for you) the instances in TSCA where EPA's practice is NOT to consider costs as part of 'unreasonable risk' determinations. The motivation for the question is section 5 exemptions, and whether EPA currently considers costs as part of deciding whether to grant them. We thought it would be useful to go through these statute-wide rather than as they occurred to us.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 10:02:52 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Udall TSCA TA request on Section 4 (4-22)

Jonathan - thanks for the additional information. Best,
Sven

On Apr 23, 2016, at 6:02 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Sorry... these documents might be better to assist you in this.

The last HLC version of Sec. 4 we saw and the page/line edits we did to it, that do not appear to have been reflected in today's document that was sent over from the House.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 6:00 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Sen. Udall TSCA TA request on Section 4 (4-22)

Jonathan,
Got it - Checking. Thanks,
Sven

On Apr 23, 2016, at 5:54 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Sven, perhaps the same exercise for Section 4 that you just did for Section 26. Attached below are the changes we sent to House folks this week and to HLC, but they appear not to have been made.

Take a look at Section 4 to see if anything catches your eye beyond the failure to make these changes. Thanks.

Conforming Amendments
Identical to 4/18 version

Double check:

- <!--[if !supportLists]--><!--[endif]-->Changing 'testing' to 'protocols and methodologies' globally

Page 5, lines 3-6: New material not in 4/18 HLC version, but appears appropriate.
Page 5, Line 20 – Change 5(d) to 5.
Page 5, Line 24 – 5(e) and 5(f) of what section 5?? Section 5 in current draft not acceptable.
Page 6, Line 7 – reinsert testing authority for 12(a)(2) in new (iv)
Page 7, Line 6 – insert "the reasonable basis for concern about the chemical substance or mixture and" after "identify"

Page 7, line 16: Strike "shall consider" and insert "shall employ"
Page 7, line 24: Strike "considering" and remove brackets on "conducting"
ADDITION by Michal per EPA – For consideration: Page 9, Line ?? – EPA TA: Add "(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would require several minor conforming changes to (b)(3), which we could provide if you are interested in this approach. This approach would maintain the existing allocation of testing responsibilities under TSCA for rules under the "old" authority but add direction for rules and order under the "new" authority. Under either of these approaches, "rule" should be stricken from the title of (b).
Page 9, Line 22 – Subsection b(3) should ONLY apply to rules, NOT to rules, orders and consent agreements. This is because in a test rule, EPA is being told to specify which entities would be required to undertake testing, based on the (3)(B)(i-iii) findings.
Page 10, Lines 12-13 – in subsection (d) – should read "identify the chemical substance or mixture for which information HAS been received."
Page 12, Line 14 – header of subsection (g) should be "Petition for protocols and methodologies for the development of information"
Page 12, Line 20 through Page 17 line 6: Animal testing provisions needs to be checked

<04-10-16sec4_04_xml.pdf>
<Section 4 (HLC 4-19).docx>
<sec4_04_xml.pdf>
<Section 4 (HLC 4-19).docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 1:06:48 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Additional Section 5 question

Michal – we are working on this morning's section 5 TA request and will have something for you shortly. Here's a response to the additional TA question.

In past drafts we've told epa to consider costs and other non-risk factors to the extent practicable using info reasonably available to epa. Needed qualifier since these are new chemicals?

Response: Yes, this is a necessary qualifier, even in the case of new chemicals. The consideration of costs and non-risk factors is generally much more limited in the case of new chemicals, largely due to the fact that ***there is no ongoing manufacture, processing, or use*** upon which to base regulatory cost estimates. Omitting the caveats about "to the extent practicable using informational reasonably available" would be a very conspicuous omission in comparison to section 6. It might give rise to arguments that Congress intended EPA to go to extraordinary lengths to predict the economic opportunity costs of not introducing a new chemical substance into commerce.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 5, 2016 at 7:43:26 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Section 5

One last q on this

In past drafts we've told epa to consider costs and other non-risk factors to the extent practicable using info reasonably available to epa. Needed qualifier since these are new chemicals?

Thx

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

On Apr 5, 2016, at 6:00 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven - comments in yellow are for you, changes marked with blank comment boxes and a couple in green for Dimitri. Pls take one more FAST look, need to get this to the House asap.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<5-04-05-16-EARLY AM.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 3:21:53 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on section 5 followup and priorities

Michal - Sounds good on section 5. Priorities for outstanding items and am I missing anything?

- section 5(a) followup – EPA standing by per your note below
- section 19 judicial review followup – you sent on 4/7@8:43pm
- section 8 nomenclature followup – you sent on 4/3@6:18pm
- section 6, replacement parts – you sent on 4/7@1:10pm

Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 11:10 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on section 5 followup

Thanks on all. Will be in touch on next steps/questions.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, April 8, 2016 10:54 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 5 followup

Michal,
This responds to the TA request following up on section 5. In addition, we received a question from Richard Denison on the section 5 TA – the question and response are included below. Perhaps a call with you and Richard to talk through this would be helpful – please let me know if you want to schedule something.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Michal TA Request (Thursday, April 07, 2016 7:23 PM)

Question: Thanks. quick alternative for you on 5(a). Would this or something like it work? could we then restore the old (b)(3)?

> **(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance, and the Administrator has conducted a review and made a determination under paragraph (3) or subsection (g), and such person complies with any applicable requirement of subsections (b), (e) or (f); and**

Response: While we'd need to see the entire section to definitively evaluate the effect of any re-write and understand which "old (b)(3)" you are referring to, we think the idea you have described below does not seem to work as you intend. Here is the logic that your language seems to establish:

Manufacture may proceed IF AND ONLY IF:

A. The manufacturer submits the information with the PMN that is required under (b).

AND

B. EPA says "May Present" OR EPA says "Not May Present" OR EPA says "Not Enough Information" OR EPA documents "Not May Present" under subsection (g).

AND

C. IF EPA establishes any requirements under (e) or (f), the manufacture is compliant with those requirements.

[Note that the last item in the string of items under B (the reference to subsection "g") is superfluous. EPA cannot document a "Not May Present" finding unless EPA makes a "Not May Present" finding. EPA cannot make a "Not May Present" finding unless EPA documents a "Not May Present Finding" under (g).]

Under this framework, the manufacturer can submit a valid notice that complies with (b), THEN EPA can conclude that there is "Not Enough Information," THEN EPA can elect not to impose any requirement under (e), AND THEN manufacture can proceed without any further follow-up, except for EPA providing the manufacture with an opportunity to provide more information.

By contrast, we believe the text edits we suggested on Thursday evening would accomplish your intent.

Denison section 5 Inquiry

I saw your latest TA provided late yesterday. Greatly appreciate your patience and careful reading of this.

Let me try to clarify what is at least my aim with this language, which I think reflects the Senate bill.

If there is not sufficient information per the (a)(3)(B) determination, the chemical can commence ONLY if either:

1) **EPA requests more information per (e)(1)(A) and when it gets information it deems sufficient, it makes the (a)(3)(A) determination; if the chem may present UR, it issues an order sufficient to allay the concern per subsection (f); if not, commencement is allowed.**

OR

2) **Pending or in lieu of getting additional information, EPA imposes conditions sufficient to allay any concern the chemical may present UR even in the absence of that information, per an order under (e)(1)(B).**

Either way an order is required unless EPA finds per (a)(3)(A) that there is not a concern the chem may present un UR.

Why is that approach a problem?

Under your proposed rewrite of (a)(1)(ii)(II), if there were initially insufficient information, EPA would have to do the second option even if it obtained the needed information, would it not, in order to allow commencement?

I read (e)(1)(A), if EPA chose that path, to require EPA to not allow market entry until it has enough information to make the UR determination. That's because (e)(1)(A)(iv) leads back to the (a)(3)(A) determination.

Do you not read it that way? What else would be needed to allow EPA to use either pathway but ensure no commencement until EPA either finds initially no basis for UR or imposes conditions sufficient to allay that concern?

Response: Richard, this responds to your question about section 5(a)(3)(B).

We have no issue with your objective but don't think the language accomplished that. The draft we reviewed would have allowed manufacture to commence if EPA:

(II) makes a determination under paragraph (3)(B) and takes the actions required under subsection (e).

Under subsection (e) as drafted, EPA could take either the (e)(1)(A) or the (e)(1)(B) route. Under (e)(1)(A), if EPA provided the submitter an opportunity to submit more info, it would have taken all actions required under (e) and manufacture could commence immediately. Note that there is no obligation in (e)(1)(A) for the submitter to submit information when given the opportunity and no obligation for EPA to issue a test rule or order if the submitter doesn't do that. And, while EPA has an obligation to make an (a)(3)(A) determination within 90 days of getting information, that obligation arises only if EPA gets information. So we think we read this differently from the way you read it.

You ask what else would be required to ensure no market entry before either an (a)(3)(A) determination with an (f) order as needed, or an (e) order. The section 5 drafts we saw before the most recent one accomplished that objective pretty well, so we would need to better understand what the concern was with that drafting to provide an alternative suggestion.

This only responds to changes since the last version at the time we were reviewing. All previously offered technical assistance is still germane to the extent the provisions have not changed since the technical assistance was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 07, 2016 7:23 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: SEPW TSCA TA on section 5

Thanks. quick alternative for you on 5(a). Would this or something like it work? could we then restore the old (b)(3)?

> (i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance, and the Administrator has conducted a review and made a determination under paragraph (3) or subsection (g), and such person complies with any applicable requirement of subsections (b), (e) or (f); and

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 10:05:48 PM
To: 'Richards, Tina' [Tina.Richards@mail.house.gov]
CC: Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]; Sarley, Chris [Chris.Sarley@mail.house.gov]
Subject: HEC TSCA TA on section 14 CBI costs

Tina,
This TA responds to the request on section 14 CBI costs.

The difference would be approximately $500,000, as an upper bound estimate. This includes roughly $250,000 in contractor costs and as much as $250,000 in personnel costs (2 FTE). We did not attempt to subtract out avoided costs if the Agency were to be requested to release the information under FOIA, as we do not have a basis to estimate this.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Richards, Tina [mailto:Tina.Richards@mail.house.gov]
Sent: Wednesday, April 27, 2016 2:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Couri, Jerry <JerryCouri@mail.house.gov>; McCarthy, David <David.McCarthy@mail.house.gov>; Sarley, Chris <Chris.Sarley@mail.house.gov>
Subject: TA question on section 14

What would be the difference in the burden (cost/time) on the agency if the agency is required to review all CBI to determine whether it still qualifies for protection and then affirmatively make information (that no longer qualifies) available to the public versus just making the information available upon request under FOIA?

Tina Richards
Counsel | Committee on Energy and Commerce
U.S. House of Representatives
259A Ford House Office Building | 202.226.5213 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 7:34:34 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Section 8
Attachments: Markey.TSCA TA.section 8.docx

Michal,
This responds to your TA request on section 8.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 4:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 8

Sven

Attached is a redline of Senate section 8 with a few changes from the reported text. Could you have your team take a look and address any issues? This can be at the back of the current queue.

Thanks
Michal

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) REPORTS.—(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 4, 5~~(b)(4)~~, or 6, or an order in effect under section 4 or section 5(~~d~~e)(4), or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7, to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

(i) review the adequacy of the standards prescribed according to subparagraph (B);

(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted; and

(iii) revise the standards if the Administrator so determines.

Commented [A1]: This mandatory periodic review, including two comment periods, will likely have little or no value, since the new 8(a)(4) authority appears to allow EPA to collect anything it could collect under 8(a)(1), with no small business exemption. Overall, we think there might be confusion about the relationship of 8(a)(1) and (a)(4).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(4) RULES.—

(A) DEADLINE.—

(i) IN GENERAL.— Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of additional information known or reasonably ascertainable by the person making the report, including rules applicable to processors, so that the Administrator has the information necessary to carry out this title.

(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

(i) to limit the potential for duplication in reporting requirements;

(ii) to minimize the impact of the rules on small manufacturers and processors; and

(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

(b) INVENTORY.—(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific

Commented [A2]: It might make sense to change the title of section 8(b) from "Inventory" to "Inventories", since it will contain two completely unrelated inventories (the TSCA Inventory and the Mercury Inventory under 8(b)(10).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(3) NOMENCLATURE.—

(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

(i) maintain the use of Class 2 nomenclature in use on date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System (SDANS) published in March 1978 by the Administrator in section 3 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and

(iii) treat all components of categories that are considered to be statutory mixtures under this Act, when present as components of such mixtures, as being included on the list established under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

(I) cement, Portland, chemicals, CAS No. 65997-15-1;

(II) cement, alumina, chemicals, CAS No. 65997-16-2;

(III) glass, oxide, chemicals, CAS No. 65997-17-3;

(IV) frits, chemicals, CAS No. 65997-18-4;

(V) steel manufacture, chemicals, CAS No. 65997-19-5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402-68-4; and

(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

(i) IN GENERAL.—In the event that existing guidance allows for multiple nomenclature conventions, the Administrator shall—

(I) maintain the nomenclature conventions for substances; and

(II) develop new guidance that—

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list established under paragraph (1); and

(bb) permits persons to rely on that new guidance for purposes of determining whether

Commented [A3]: The drafting here is imprecise, especially since the items in the list are chemical substance, not mixtures. (In the past, EPA called these chemical substances "statutory mixtures" but this terminology is not current practice, is generally confusing, and is unnecessary to accomplish the intended policy objective of ensuring that these substances remain on the Inventory exactly as they were described in 1985.) It is unhelpful to blur the basic definitional terms "chemical substance" and "mixture," which are elsewhere defined as separate concepts by statute. This could lead to debate elsewhere about the operation of TSCA (e.g., whether EPA can or must do safety assessments on mixtures).

The addition of the phrase "when present as components of such mixtures," does not fully clarify matters, because it does not address when a particular combination of substances would qualify as one of these listed substance. There is, in fact, nothing under "this Act" that sheds light on this question. The answer is found in the TSCA Inventory listings for the chemical substance. Therefore, EPA recommends the following redraft, which will more clearly accomplish the apparent policy objective of this language: **"treat all chemical substances described by the following category listings, when manufactured as described in Appendix A of column I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a), as being . . ."**

Commented [A4]: We assume that this refers only to EPA guidance, and suggest clarification. Additionally, EPA is unaware of any existing EPA guidance that allow for multiple nomenclature conventions, meaning that these provisions would be completely inoperative. Nonetheless, note that the SEPW Report on p. 20, states that "numerous nomenclature conventions exist that they may prevent the efficient distribution of chemicals into commerce." EPA does not understand what the report is alluding to, complicating our interpretation of this language.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

a chemical substance is on the list established under paragraph (1)].

(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

(4) CHEMICAL SUBSTANCES IN COMMERCE.—

(A) RULES.—

(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and allow processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

(iv) LIMITATION.—No substance on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph or be subject to Section 5 of this Act by reason of a change to active status under paragraph (5)(B)].

(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating the rule established pursuant to subparagraph (A), the Administrator shall—

(i) maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

(ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14 submit a notice under subparagraph (A) that includes such request;

~~require a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published~~

Commented [A5]: SEPW Report on page 20 suggests that the general objective is to allow new substances "similar" to existing chemical substances to be treated as existing chemical substances. Note that it has not been EPA's practice or interpretation of TSCA to treat substances substances that are similar in some respect to substances on the inventory as the same chemical substances, and EPA does not believe this practice would be consistent with standard chemical nomenclature conventions. Thus, if this language is not wholly inoperative, it will be the subject to considerable interpretive debate.

Commented [A6]: This language would never become operative. At such time as EPA determined that a single chemical substance appeared twice on the TSCA Inventory, EPA would delete the duplicate entry, thereby not triggering the statutory duty.

Commented [A7]: It would be clearer to say by reason of being designated an inactive chemical substance under this subparagraph.

Commented [A8]: Note that this means EPA cannot treat the re-activation of a chemical substance as a prompt to issue a SNUR for that substance. Was that the objective?

If the objective is simply to reassure industry that being moved back to active would not require the submission of a PMN, that should be clear simply from the prior sentence, which makes clear that the chemical was never removed from the list of existing chemical substances in the first place.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

(iii) require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C); and

(iv) move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure of the specific identity of the substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list.

(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B).

(D) REQUIREMENTS OF REVIEW PLAN.—Under the review plan under subparagraph (C), the Administrator shall—

(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

(ii) in accordance with section 14—

(I) review each substantiation—

(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

(II) approve, ~~modify~~approve in part, or deny each claim; and

(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case

Commented [A9]: What is EPA supposed to do with inactive chemical substances for which no request was received to maintain an existing claim for protection against disclosure?

Under (ii) there was an obligation for any such claimant to submit a re-substantiation notice of their claim that the Chem ID is confidential. Would the consequence of failure to do so be that they waive their claim and the chemical is also moved to the non-confidential portion of the Inventory?

Is yes, why is that excluded from discussion here?
If no, what was the point of the original requirement that they submit a re-substantiation notice?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(iii) encourage manufacturers or and processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

(E) TIMELINE FOR COMPLETION OF REVIEWS.—

(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

(ii) CONSIDERATIONS.—

(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of claims needing review and the available resources.

(II) ANNUAL REVIEW GOAL AND RESULTS.—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

(5) ACTIVE AND INACTIVE SUBSTANCES.—

(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

(B) CHANGE TO ACTIVE STATUS.—

(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

(I) in the notice submitted under clause (i), assert the claim; and

(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

Commented [A10]: Unlike other provisions of the bill under which EPA is given authority to specify the manner of CBI assertion and substantiation, there is no such authority here. If the intent is for EPA to have such authority, it could be added.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

(I) designate the applicable chemical substance as an active substance;

(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, ~~modify~~ approve in part, or deny the claim;

(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

(C) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

(7) PUBLIC INFORMATION.—Subject to this subsection, the Administrator shall make available to the public—

(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

(i) an active substance; or

(ii) an inactive substance;

(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(C) subject to subsections (f) and (g) of section 14, the specific identity of any active substance for which—

(i) a claim for protection against disclosure of the specific identity of the active ~~chemical~~ substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;

(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive ~~chemical~~ substance for which a notice is received under paragraph (4)(A)(i) or (5)(~~C~~E)(i) that is not on the confidential portion of the list published under paragraph (1).

(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors shall be required—

(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.

(10) MERCURY.—

(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 3(2)(B), the term 'mercury' means—

(i) elemental mercury; and

(ii) a mercury compound.

(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

(i) identify any remaining manufacturing processes or products that intentionally add mercury; and

(ii) recommend actions, including proposed revisions of Federal law (including regulations), to achieve further reductions in mercury use.

(D) REPORTING.—

(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

Commented [A11]: Note that the "rules required under this subsection" will include the mercury rule EPA promulgates under the new 8(b)(10)(D), added by section 29 of the bill. So this certification will be required for submission under that rule as well as under the preceding inventory rules.

Commented [A12]: This seems unnecessary and has potential negative implications for EPA's interpretation of the MEBA provisions already codified in TSCA sections 6 and 12. EPA has interpreted those provisions as covering even mercury that does not qualify as a chemical substance under section 3(2)(B) of TSCA, and the inclusion of the notwithstanding clause here could call that interpretation into question. Also, the bill does not add a "notwithstanding" provision in the mercury amendments relating to section 12(c).

Commented [A13]: It is not clear what EPA is supposed to do here with respect to regulations. Is the intent that EPA recommend proposed regulations? Are we making that recommendation to ourselves? And does the bill give EPA additional rulemaking authority for this purpose?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

(iii) EXEMPTION.—This subparagraph shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.

Commented [A14]: EPA has interpreted the existing MEBA provisions codified in sections 6 and 12 as generally not covering mercury waste. There is some concern that the specific exemption here in 8(b) will call that general interpretation into question.

(c) RECORDS.—Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) HEALTH AND SAFETY STUDIES.—The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—

(1) IN GENERAL.—Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(2) ADDITIONAL INFORMATION.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health or the environment.

(f) DEFINITIONS.—~~For purposes of this section,~~ In this section:

(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

(C) for which a notice is received under subsection (b)(5)(C).

(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

(3) MANUFACTURE; PROCESS.—The terms "manufacture" and "process" mean manufacture or process for commercial purposes.

[15 U.S.C. 2607]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 4:14:16 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: TSCA TA on HLC section 4 (4-18)
Attachments: Markey.TSCA TA.Section 4 SENATE TO HOUSE (4-18).docx

Michal, Jonathan and Adrian,
The attached TA responds to the request to compare section 4 - SLC and HLC (4-18) versions.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.
Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SECTION 4 AS AMENDED BY ~~SENATE~~HOUSE

§2603. Testing of chemical substances and mixtures

(a) Testing requirements

(1) If the Administrator finds that—

(~~1~~)(A)(i)(I) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(~~i~~II) there ~~are~~is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(~~ii~~III) testing of such substance or mixture with respect to such effects is necessary to develop such information; or

(~~B~~)(ii)(I) a chemical substance or mixture is or will be produced in substantial quantities, and (~~I~~aa) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (~~II~~bb) there is or may be significant or substantial human exposure to such substance or mixture,

(~~i~~II) there ~~are~~is insufficient information and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(~~ii~~III) testing of such substance or mixture with respect to such effects is necessary to develop such information; ~~or~~and

(~~2~~B) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

~~"(b) Development of New Information.—~~

~~"(1) IN GENERAL.—~~(2) ADDITIONAL TESTING AUTHORITY.—In addition to the authority provided under ~~paragraphs (1) and (2) of subsection (a~~paragraph (1), the Administrator may, by [rule,]1, order, or consent agreement—

~~"~~(

(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(

(i) to review a notice under section 5(d) or to perform a risk evaluation under section 6;

"((ii) to implement a requirement imposed in a rule, order, or consent agreement~~, or order issued~~ under subsection (e) or (f) of section ~~5(e) or 5(f)~~ or under a rule promulgated under section 6(a); or

~~"((iii) pursuant to section 12(a)(4); or~~

"~~(iv)~~ at the request of ~~the~~a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure; and

"(

(B) require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that ~~the~~such information is necessary to establish the priority of the ~~chemical~~ substance, subject to the limitations that—

"(

(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement~~, or order issued~~ under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance; and

"(

(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

~~"(2) IDENTIFICATIONS REQUIRED~~

(3) STATEMENT OF NEED.—When requiring the development of new information relating to a chemical substance or mixture under paragraph (~~1~~2), the Administrator shall—

"~~(A)~~ identify ~~a reasonable basis for concern about the chemical substance or mixture and~~ the need for the new information~~;~~

"~~(B)~~, describe how information reasonably available to the Administrator was used to inform the decision to require new information~~;~~

"~~(C)~~, explain the basis for any decision that requires the use of vertebrate animals~~;~~, and

"~~(D)~~, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

~~"(3) TIERED SCREENING AND TESTING PROCESS~~

(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

~~["(4) RELATIONSHIP TO OTHER LAW.—For purposes of this Act, a rule, order, or consent agreement issued under this subsection shall be treated as a rule, order, or consent agreement issued under subsection (a)."; [suggested addition to capture applicability of other provisions in TSCA to this new subsection in the same way as the other provisions~~

Commented [A1]: Not that EPA will not be able to use orders or consent agreements to test for unreasonable risk from exported chemicals but will instead have to rely on testing by rule under the current TSCA test standards.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

~~apply to subsection (a)]]~~

~~(c~~

(b) Testing requirement rule~~, order, or consent~~ agreement

(1) A rule, order, or consent agreement under subsection (a) of this section shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule, order, or consent agreement,

(B) protocols and methodologies for the development of information for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator information developed in accordance with the protocols and methodologies referred to in subparagraph (B).

In determining the protocols and methodologies and period to be included, pursuant to subparagraphs (B) and (C), in a rule, order, or consent agreement under subsection (a) of this section, the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule, order, or consent agreement. Any such rule, order, or consent agreement may require the submission to the Administrator of preliminary ~~information~~data during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which protocols and methodologies for the development of information may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential ~~exposure~~ to humans or the environment. The characteristics of chemical substances and mixtures for which such protocols and methodologies may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such protocols and methodologies include epidemiologic studies, serial or tiered testing, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health. [The Administrator shall reduce the use of animals in the testing of chemical substances or mixtures, to the extent practicable, by taking into consideration existing toxicity information and the availability of validated alternative test protocols that reduce or replace animal tests.]

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the protocols and methodologies for development of information prescribed in rules, orders, ~~or~~and consent agreements under subsection (a) of this section and shall, if

Commented [A2]: Not clear why stricken, since (b) by its terms applies to all.

Commented [A3]: Why changed here? Otherwise this version seems to adopt the Senate use of "information".

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

necessary, institute proceedings to make appropriate revisions of such protocols and methodologies.

(3)(A) A rule under subsection (a) of this section respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit information to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such information on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit information on a chemical substance or mixture subject to a rule under subsection (a) of this section:

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(~~iii~~)(II) or (a)(1)(~~B~~A)(ii)(II) of this section with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(~~iii~~)(II) or (a)(1)(~~B~~A)(ii)(II) of this section with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(~~iii~~)(II) or (a)(1)(~~B~~A)(ii)(II) of this section with respect to the distribution in commerce, use, or disposal of such substance or mixture.

Commented [A4]: This will cover both "old style" TSCA rules and rules under the new (a)(2) authority. Note that the provisions of (B) require EPA to impose testing obligations on ALL manufacturers and/or processors of the chemical substance to be tested, so if EPA elects to proceed with a rule under (a)(2), it will not be able to target the rule to specific entities. But that may well be ok, since EPA can elect to use orders of CAs under (2), which are not subject to this provision.

(4) Any rule, order, or consent agreement under subsection (a) of this section requiring the testing of and submission of information for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (~~d~~c)(3)(B) of this section) which is applicable to information for such substance or mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order, or consent agreement under subsection (a) of this section requiring the testing of and submission of information for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to information for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

~~(5) Rules issued under subsection (a) of this section (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5.~~

(~~d~~ (c) Exemption

(1) Any person required by a rule or order under subsection (a) of this section to conduct tests and submit information on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which information has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a)

or for which information is being developed pursuant to such a rule, order, or consent agreement, and

(B) submission of information by the applicant on such substance or mixture would be duplicative of information which has been submitted to the Administrator in accordance with such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement-,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting information on such substance or mixture under the rule or order with respect to which such application was submitted.

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information on a chemical substance or mixture is granted on the basis of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such information, for a portion of the costs incurred by such person in complying with the requirement to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any information for a chemical substance or mixture is a period—

(i) beginning on the date such information is submitted in accordance with a rule, order, or consent agreement ~~promulgated~~ under subsection (a) of this section, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such information,

whichever is later.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information on a chemical substance or mixture is granted on the basis of the fact that information is being developed by one or more persons pursuant to a rule, order, or consent agreement ~~promulgated~~ under subsection (a) of this section, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under ~~rule, order, or consent agreements~~rules of the Administrator)—

(i) to each such person who is developing such information, for a portion of the costs incurred by each such person in complying with such rule, order, or consent agreement, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, order, or consent agreement, for a portion of the amount such person was required to contribute.

In promulgating ~~rule, order, or consent agreements~~rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing information pursuant to a rule, order, or consent agreement ~~promulgated~~ under subsection (a) of this section and if after such exemption is granted the Administrator determines that no such person has complied with such rule, order, or consent agreement, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule, order, or consent agreement with respect to which such exemption was granted.

(e~~d~~) Notice

Upon the receipt of any information pursuant to a rule, order, or consent agreement under subsection (a) of this section, the Administrator shall publish a notice of the receipt of such information in the Federal Register within 15 days of its receipt. Subject to section 2613 of this title, each such notice shall (1) identify the chemical substance or mixture for which information ~~has~~have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable protocols and methodologies for the development of information; and (3) describe the nature of the information developed. Except as otherwise provided in section 2613 of this title, such information shall be made available by the Administrator for examination by any person.

Commented [A5]: wrong

(f~~e~~) Priority list

(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority

consideration for the development of information under subsection (a) of this section. In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of information concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of information upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances andmixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) of this section with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a) of this section. The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after January 1, 1977, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the ~~preceding~~preceeding [1] sentence, the committee shall make such previsions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Administrator shall with respect to such chemical substance or mixture either issue an order ~~or~~, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a~~) of this section~~), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order ~~or~~, entering into such a consent agreement, or initiating such a proceeding .

Commented [A6]: Seems like "either" should drop

(2)(A) The committee established by paragraph (1)(A) shall consist of ~~10~~ten members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.].

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(~~ix~~x) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of the U.S. Food and ~~Drugs~~Drug Administration from employees of the ~~Food and Drug~~ Administration.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii) Initial appointments to the committee shall be made not later than the 60th day after January 1, 1977. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this chapter or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this chapter or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(gf) Required actions

Upon the receipt of—

(1) any information required to be submitted under this chapter, or

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings , the Administrator shall, within the 180-day period beginning on the date of the receipt of such -information, initiate applicable action under section 2604, 2605, or 2606 of this title to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, made without consideration of costs or other nonrisk factors, that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5. This subsection shall not take effect until two years after January 1, 1977.

~~(h) Protocols~~g) Petition for protocols and ~~Methodologies~~methodologies for the ~~Development~~development of ~~Information~~information

A person intending to manufacture or process a chemical substance for which notice is required under section 2604(a) of this title and who is not required under a rule, order, or consent agreement under subsection (a) of this section to conduct tests and submit information on such substance may petition the Administrator to prescribe protocols and methodologies for the development of information for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such protocols and methodologies for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 2613 of this title, in the Federal Register the reasons for such denial.

~~"(i) Reduction of Testing on Vertebrates.—~~

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

~~"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures under this Act, by—~~

~~"(A) prior to making a request or adopting a requirement for testing using vertebrate animals and in accordance with subsection (b)(2), taking into consideration, as appropriate and to the extent practicable, reasonably available existing information, including—~~

~~"(i) toxicity information;~~

~~"(ii) computational toxicology and bioinformatics; and~~

~~"(iii) high-throughput screening methods and the prediction models of those methods; and~~

~~"(B) encouraging and facilitating—~~

~~"(i) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;~~

~~"(ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category; and~~

~~"(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests.~~

~~"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—~~

~~"(A) not~~[(h) REPORTS ON PROGRESS IN REDUCING THE USE OF ANIMAL TESTING.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, ~~develop a strategic plan to promote~~and every 5 years thereafter, the ~~development and implementation~~Administrator shall submit to Congress a report that describes the progress made in reducing and replacing animal tests through the use of validated alternative test ~~methods and testing strategies to reduce, refine and replace animal testing~~protocols for assessing risks of injury to health or the environment of chemical substances or mixtures ~~through, for example—~~:

~~"(~~(2) INCLUSION.—A report submitted under this subsection shall include information regarding the extent to which testing is conducted using information developed through—

(A) computational toxicology and bioinformatics;

~~"(ii~~(B) high-throughput screening methods;

~~"(iii~~(C) testing of categories of chemical substances;

~~"(iv~~(D) tiered testing methods;

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

~~"(v) toxicity pathway-based risk assessments;~~

~~"(vi) in vitro studies;~~

~~"(vii) systems biology;~~

~~"(viii)~~(E) new or revised methods identified by ~~validation bodies such as~~ the Interagency Coordinating Committee on the Validation of Alternative Methods ~~or the Organization for Economic Cooperation~~, and ~~Development; or~~

~~"(ix)~~(F) industry consortia that jointly develop ~~testing data submitted under this Act;~~

~~"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;~~

~~"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies, which should be updated on a rolling basis, that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;~~

~~"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);~~

~~"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods implementation; and~~

~~"(F) prioritize and carry out performance assessment, validation, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.~~

~~"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—~~

~~"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;~~

~~"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—~~

~~"(i) the chemical substance cannot be absorbed; or~~

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(ii) testing for a specific endpoint is technically not practicable to conduct, or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability, before conducting new animal testing.

"(B) RELATIONSHIP TO OTHER LAW.—A violation of this paragraph shall not be a prohibited act under section 15.".

(b) Conforming Amendments.—[Once all of the sections are rolled together into 1 draft, need to check the TSCA conforming amendments below against the other section text.]

(1) Section 5(b)(1)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2604(b)(1)(B)(ii)) is amended by striking "section 4(c)" and inserting "section 4(d)".

(2) Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601) is amended by striking "section 4(f)" and inserting "section 4(g)".

."]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 11:13:39 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the additional followup request on 6/26.

In response to your request for drafting assistance to ensure that all relevant guidance documents are included in the scope of the Section 26 provision, we suggest the following:

26(_) [Nothing requires EPA to revise or withdraw an action] . . . "solely because the action was completed prior to the development of a policy, procedure, or guidance under this section or under section 6."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 10, 2016 at 6:31:09 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA additional follow up on section 6/26

ok. thanks. so, given that, I'm planning to move 3. Into 26. The other 2 can't be addressed that way. using House text as your base, I think I need some drafting assistance. I'm afraid that sentence the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure." can't be included.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey


<image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 4:21 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the followup request on 6/26.

We think there are 3 relevant requirements.

1. the requirement in 6b1 to establish by rule a risk-based screening process

2. the requirement in 6b4B to establish by rule the process for risk evaluations

3. The requirement in 6b4I to issue guidance as to how outside parties can submit their own draft risk evaluations

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 10, 2016 at 1:58:35 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA follow up on section 6/26
I understand. I am attaching the Senate's view of what section 6 looks like to resolve this concern for you. it has not yet been sent to the House despite its file name – I am hoping to resolve this section 26 issue before that occurs.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 2:57:10 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sec. 26 T.A.

Got it

On Mar 16, 2016, at 10:54 AM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Please use this one...

Would like to check with you on the impact of making these changes to the Senate offer...

26(b)(4) do the following:

- Include such amounts as are deposited in the Fund under this paragraph with (4)(A)
- Strike (4)(A)(ii) and (iii)
- Strike (B)(ii)(III) [I know our intent it to section off TSCA money, but I'm not sure what it means]
- Strike (4)(C)
- Add House passed (b)(3)(e) "Accounting and Auditing"
- We have already taken their "Auditing" language and struck ours.
- They are keeping our "Termination" language

<image001.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 2:31:09 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on closed sections

Ok - thanks

On Apr 15, 2016, at 10:29 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Ok. Pls drop and do the two section 6 requests first. Then back to pbt. Then to 26.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, April 15, 2016 10:26 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on closed sections

Thanks- will relay. There's a lot on the plate do please let me know if you need anything right away. Working on PBts and section 26 now. Thanks,
Sven

On Apr 15, 2016, at 10:24 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

We know. That definition is likely accepted but is part of a broader set of negotiations on a final package and thus none of that stuff is reflected here.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, April 15, 2016 10:22 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on closed sections

Michal,
Thanks for sending the closed sections.

We would note that the "closed" Section 3 did not include a definition of "complex durable goods." If that concept is to be included in Section 6, the definition is essential to implementation/workability.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

> On Apr 14, 2016, at 5:07 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Some you have seen some you have not

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 10:02:27 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request on section 8 nomenclature language
Attachments: Nomenclature (3-21).docx

Michal – while understanding the TA request's urgency, given schedules and the specific technical and legal knowledge required on nomenclature, we need to hold off responding fully until Monday. We have concerns about (B)(i) and need more time to articulate them. Please let me know right away if that is a problem.

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the TSCA inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include byproducts that do not appear on the TSCA inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

Response: Although not able to fully respond yet, we have several concerns, including that the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six, creating the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

Response: EPA has no concerns with the (B)(ii) language

We continue to work on this TA request, please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Sent: Monday, March 21, 2016 7:08 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: Time-sensitive on section 8

Sven

Can you pls rush the review of this redlined text to portions of section 8?

Here are the basic questions:

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the tsca inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include biproducts that do not appear on the tsca inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

I think there is a desire to get this to the House asap.

Thanks
M
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

(iii) treat the categories of combinations considered to be statutory mixtures under this Act, and their components when present in such mixtures, as being included on the list established under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation--

or

(iii) include on the list established under paragraph (1), under the Chemical Abstracts Service numbers for the respective categories, the combinations considered to be statutory mixtures under this Act, and their components when present in such mixtures, including, without limitation ~~treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation~~—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—~~If an existing guidance allows for multiple nomenclature conventions, t~~The Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance determined by the Administrator, following a request by a manufacturer or processor that the Administrator review information reasonably available to the Administrator, to appear~~ing~~ multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall ~~develop guidance~~ recognize~~ing~~ the multiple listings as a single chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 10:00:04 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Udall TSCA TA request on Section 4 (4-22)

Jonathan,
Got it - Checking. Thanks,
Sven

On Apr 23, 2016, at 5:54 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Sven, perhaps the same exercise for Section 4 that you just did for Section 26. Attached below are the changes we sent to House folks this week and to HLC, but they appear not to have been made.

Take a look at Section 4 to see if anything catches your eye beyond the failure to make these changes. Thanks.

Conforming Amendments
Identical to 4/18 version

Double check:

- <!--[if !supportLists]--><!--[endif]-->Changing 'testing' to 'protocols and methodologies' globally

Page 5, lines 3-6: New material not in 4/18 HLC version, but appears appropriate.
Page 5, Line 20 – Change 5(d) to 5.
Page 5, Line 24 – 5(e) and 5(f) of what section 5?? Section 5 in current draft not acceptable.
Page 6, Line 7 – reinsert testing authority for 12(a)(2) in new (iv)
Page 7, Line 6 – insert "the reasonable basis for concern about the chemical substance or mixture and" after "identify"
Page 7, line 16: Strike "shall consider" and insert "shall employ"
Page 7, line 24: Strike "considering" and remove brackets on "conducting"
ADDITION by Michal per EPA – For consideration: Page 9, Line ?? – EPA TA: Add "(C) A rule or order under subsection (a)(2) may require the development of information by any person who manufactures or processes or intends to manufacture or process a chemical substance or mixture subject to the rule or order." This would require several minor conforming changes to (b)(3), which we could provide if you are interested in this approach. This approach would maintain the existing allocation of testing responsibilities under TSCA for rules under the "old" authority but add direction for rules and order under the "new" authority. Under either of these approaches, "rule" should be stricken from the title of (b).
Page 9, Line 22 – Subsection b(3) should ONLY apply to rules, NOT to rules, orders and consent agreements. This is because in a test rule, EPA is being told to specify which entities would be required to undertake testing, based on the (3)(B)(i-iii) findings.
Page 10, Lines 12-13 – in subsection (d) – should read "identify the chemical substance or mixture for which information HAS been received."

Page 12, Line 14 – header of subsection (g) should be "Petition for protocols and methodologies for the development of information"
Page 12, Line 20 through Page 17 line 6: Animal testing provisions needs to be checked

<04-10-16sec4_04_xml.pdf>
<Section 4 (HLC 4-19).docx>

Appointment

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/16/2016 7:34:04 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]

Subject: Senate TSCA TA - Unreasonable Risk and section 5 exemptions
Location: Call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy

Start: 2/18/2016 9:30:00 PM
End: 2/18/2016 10:30:00 PM
Show Time As: Tentative

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 3:19:05 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Senate TSCA TA on section 5

Go to bed!

On Apr 4, 2016, at 11:15 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Well anyway I switched to bourbon. But yay for nova I guess. :-)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Monday, April 4, 2016 11:10 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Senate TSCA TA on section 5

It's s pleasure - Nova up 6 with 4 min to go.

On Apr 4, 2016, at 11:06 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks very much

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Monday, April 4, 2016 11:04 PM
To: Freedhoff, Michal (Markey)
Cc: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Senate TSCA TA on section 5

Michal,
The attached TA responds to the request on section 5. Note that the RLSO and comments in the side margins might not show up on if reading on a phone. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 04, 2016 8:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Black, Jonathan (Tom Udall)

<Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: section 5 - for fast turnaround

Sorry this took longer than expected. Please have your team review ASAP, tonight idea.
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 1:08:36 AM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on SLC section 5 (4-12)
Attachments: Markey.TSCA TA.section 5 (4-12).docx

Michal – see attached TA on section 5.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 10:33 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 5

Pls have your team review this as well.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Contreni, Maureen (SLC)
Sent: Tuesday, April 12, 2016 10:32 AM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley); Karakitsos, Dimitri (EPW)
Cc: Johnson-Weider, Michelle (SLC); Edwards, Deanna (SLC)
Subject: TSCA sec 5 (MCC16324)

Hi All,

Attached please find your updated draft of the insert for TSCA sec. 5 (MCC16324). To answer your question, the text that is bracketed contains cross-references that we need to check when we compile all of the inserts into one document.

Maureen

From: Freedhoff, Michal (Markey)
Sent: Tuesday, April 12, 2016 6:50 AM
To: Johnson-Weider, Michelle (SLC); Contreni, Maureen (SLC)
Cc: Karakitsos, Dimitri (EPW)
Subject: Sorry, use this version of 5. Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. ___. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking "test data" each place it appears and inserting "information";

(2) by striking "data" each place it appears and inserting "information";

(3) in subsection (a)—

(A) in paragraph (1), by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and indenting accordingly;

(B) by striking "(a) In General.—(1) Except" and inserting the following:

"(a) Notices.—

"(1) PROHIBITION AND REQUIREMENT.—

"(A) PROHIBITION.—Except";

(C) in subparagraph (A) (as so designated)—

(i) in the undesignated matter at the end, by striking "unless such person" and inserting the following: "unless the requirements of subparagraph (B) are fulfilled.

"(B) REQUIREMENTS.—Subparagraph (A) does not apply if—

"(i) a person described in that subparagraph";

(ii) by striking "requirement of subsection (b)." and inserting the following: "requirement of or imposed under subsections (b), (e), or (f); and

"(ii) the Administrator conducts a review of the notice; and

"(I)(aa) makes a determination under paragraph (3)(A) and, as necessary, issues an order to restrict such manufacturing or processing under subsection (f)(1); or

"(bb) makes a determination under paragraph (3)(B) and issues an order under subsection (e)(1)(B).''; and

(D) by adding at the end the following:

"(3) REVIEW.—Before the end of the applicable period for review under paragraph (1), and subject to section 18, the Administrator shall review a notice received under paragraph (1) and—

"(A) determine whether the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without

Commented [A1]: "Requirement" should probably be plural.

Commented [A2]: This is a new structure, which seems problematic. (A) provides that no one can commence manufacturing or processing of new a new chem or for new use except in compliance with (B), then (B) says that (A) doesn't apply if B is satisfied. That doesn't really make sense. Why re-word from current law? If it must be reworded, it would make more sense to start (B) by saying "The requirements of subparagraph (B) are fulfilled if" instead of "Subparagraph (A) does not apply if".

Commented [A3]: Is there a reason this language is included here re the (f) order but not included in (bb) re the (e) order?

Commented [A4]: EPA TA: Why designate the first clause as (I)(aa) and the second clause as (bb)? Shouldn't this just be (I) and (II)?

Commented [A5]: TA request: Would it would to replace this with: "Within 90 days of receipt of a notice under paragraph (1), or of receipt of information submitted pursuant to subsection (b) or (e) that the Administrator finds sufficient to support the determination under subsection (a)(3)A), and subject to any extensions of such review period pursuant to subsection (c) or (e)"

Commented [A6R5]: EPA TA: On further review, we now see better the issue you were trying to address with respect to (b) and (e). Our recommendation, consistent with past TA, is to develop one formulation that describes the period, including extensions, and use it consistently throughout the section, except where you mean something different. You could say: "Before the end of the applicable review period [or notification and review period] under (1), (b), (c) or (e). . . ." In adapting this phrase for other subsections, you would need to change the reference to "(1)" to "(a)" or "(a)(1)".

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and take applicable action under subsection (f) or (g); or

"(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (e).

"(4) FAILURE TO RENDER DETERMINATION.—

"(A) IN GENERAL.—The Administrator shall complete a review of a notice required by this section within the review period provided in this subsection and subsection (c).

"(B) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period, including an extension pursuant to subsection (c), and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make the determination.

"(C) LIMITATIONS.—

"(i) IN GENERAL.—A refund of applicable fees under subparagraph (B) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or (e) or has otherwise unduly delayed the process so that the Administrator is unable to render a determination within the applicable period of review.

"(ii) NO DECISION.—A failure of the Administrator to render a decision shall not be considered a withdrawal of the notice.

"(iii) RELATIONSHIP TO OTHER LAW.—Nothing in this paragraph relieves the Administrator or the submitter of the notice from any requirement of this section.

"(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.";

(4) in subsection (b)—

(A) in the subsection heading, by striking "Test Data" and inserting "Information";

(B) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "rule promulgated" and inserting "rule, order, or consent

Commented [A7]: Note: if there are concerns about whether (3) above adequately accounts for (b) and (e), doesn't this raise the same concerns? Seems best to stick with one formulation.

Commented [A8]: (b) and (e)? This is really important – otherwise EPA will have to refund money despite an extension (including an agreed extension) under (e).

Commented [A9]: This seems redundant of (C)(iii) below

Commented [A10]: Doesn't really seem like the right title. The rest of section 5 doesn't seem like "other law"

agreement"; and

(II) by inserting ", order, or consent agreement" after "such rule";

(ii) in subparagraph (B)(ii), by striking "promulgated" and inserting "or order"; and

(iii) in the undesignated matter at the end—

(I) by inserting "or order" after "such rule";

(II) by striking "subsection (a)(1)(A)" and inserting "subsection (a)(1)(A)(i)"; and

(III) by striking "subsection (a)(1)(B)" and inserting "subsection (a)(1)(A)(ii)";

(C) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (ii), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(II) in the undesignated matter at the end, by striking "shall" and inserting "may"; and

(ii) in subparagraph (B)—

(I) in the matter preceding clause (i), by striking "Data" and inserting "Information";

(II) in clause (i), by striking "subsection (a)(1)(A)" and inserting "subsection (a)(1)(A)(i)"; and

(III) in clause (ii), by striking "subsection (a)(1)(B)" and inserting "subsection (a)(1)(A)(ii)";

(D) in paragraph (3)—

(i) by striking "Data" and inserting "Information"; and

(ii) by inserting "of this subsection or under subsection (e)" after "(2)"; and

(E) in paragraph (4)—

(i) in subparagraph (A)(i), by inserting ", without consideration of costs or other nonrisk factors" before the period at the end; and

(ii) in subparagraph (C), by striking ", except that" and all that follows through "subparagraph (A)";

(5) in subsection (c)—

(A) in the subsection heading, by inserting "and Review" after"Notice"; and

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(B) in the first sentence, by striking ", prescribed by" and all that follows through "begin." and inserting "prescribed by subsection (a) or (b).";

(6) in subsection (d)—

(A) in paragraph (2)—

(i) in subparagraph (B), by striking "uses or intended uses of such substance" and inserting "uses of the substance identified in the notice and any additional uses of the substance that are reasonably foreseeable by the Administrator"; and

(ii) in subparagraph (C), by inserting ", order, or consent agreement" after "rule"; and

(B) in paragraph (3), by striking "notification" both places it appears;

(7) by striking subsections (e) through (g) and inserting the following:

"(e) Regulation When Available Information Is Insufficient.—

"(1) IN GENERAL.—If the Administrator determines that the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) for a chemical substance or significant new use with respect to which notice is required by subsection (a)—

"(A) the Administrator—

"(i) shall provide an opportunity for the submitter of the notice to submit the additional information within the applicable notification and review period under subsection (a), (b), or (c);

"(ii) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(iii) may extend the notification and review period and promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

"(iv) on receipt of additional information within the time prescribed pursuant to (i), (ii), or (iii) that the Administrator finds supports the determination under subsection (a)(3)(A), which shall automatically extend the notification and review period for 90 days, shall make the determination not later than 90 days after receipt of the information; and

"(B) the Administrator may issue an order to take effect on the expiration of the applicable notification and review period under subsection (a), (b), or (c) to prohibit, or otherwise restrict, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or any combination of such activities, sufficient to allay the initial concern of the Administrator that, in the absence of sufficient

Commented [A11]: Note that (d)(3) still refers to the expiration of the period under a, b, or c and does not account for extensions under e.

Commented [A12]: Related to the TA above as to the review period: the structure of (e)(1)(A) contributes to the problem by merely *allowing* EPA to extend the period but then providing that EPA must act under a3A, despite the fact that the review period may not have been extended. We suggest the edits in the text to resolve this issue. We don't perceive that these change the intended effect but rather effectuate what we understand to be the intent.

Commented [A13]: Presumably it would be impossible (or nearly so) to get a test rule or order out, and get the info back, within the review period.

Commented [A14]: This is needed because, without it, this 90 days of review would be occurring outside the review period, which we don't appear to have authority to do under (a)(3).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

information, the substance or significant new use may present an unreasonable risk.

"(2) CONSIDERATIONS.—In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors.

"(3) COMPLIANCE WITH ORDER.—If the Administrator issues an order under paragraph (1), the submitter of the notice under subsection (a) may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this paragraph only in compliance with the restrictions specified in the order.

"(4) SIGNIFICANT NEW USE.—Not later than 90 days after issuing an order under paragraph (1), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(5) NOTIFICATION.—An order may not be issued under paragraph (1) respecting a chemical substance—

"(A) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of the substance under subsection (a), (b), or (c); and

"(B) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of the substance of the determination which underlies the order.

"(f) Protection Against Potential Unreasonable Risks.—

"(1) IN GENERAL.—If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may present an unreasonable risk of injury to health or environment in accordance with subsection (a)(3)(A)—

"(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable notification and review period under subsection (a), (b), or (c), to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to allay the initial concern of the Administrator that the substance or significant new use may present an unreasonable risk;

"(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in the order; and

Commented [A15]: Should add "of injury to health or the environment". That should always follow "unreasonable risk".

Commented [A16]: Should have comma after "use".

Commented [A17]: Need to add (e), to account for (f) orders EPA issues following review of info obtained under an (e) extension.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(2) CONSIDERATIONS.—In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall, to the extent practicable based on reasonably available information, consider costs and other nonrisk factors.

"(3) INCLUSIONS.—An order issued by the Administrator to meet the standard under paragraph (1) may include—

"(A) a requirement limiting the amount of the chemical substance which may be manufactured, processed, or distributed in commerce;

"(B) a requirement described in paragraph [(2), (3), (4), (5), (6), or (7) of section 6(a)]; or

"(C) any combination of the requirements referred to in subparagraph (B).

"(4) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance that is subject to the requirements of this subsection and that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance, to the maximum extent practicable.

"(5) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(g) Statement of Administrator Findings.—

"(1) IN GENERAL.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not warranted, then notwithstanding any remaining portion of the period for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of the substance or of the substance for a significant new use—

"(A) the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use;

Commented [A18]: Per earlier TA, we continue to wonder why (A) and (B) aren't merged into a single provision authorizing EPA to issue any restrictions allowed under 6(a). If a reference to "all uses" is added to TSCA 6(a)(2) per the Senate offer, this is probably harmless, but on its face (A) omits the portion of 6(a)(1) allowing EPA to prohibit manufacture, processing and distribution in commerce, and EPA will not be able to issue such a prohibition if the senate offer language does not stick. We also continue to wonder why the allowable order conditions are constrained for (f) orders – issued upon a "may present" finding – but not for (e) orders – issued based only on lack of information.

Commented [A19]: Or (e)?

Commented [A20]: This highlighted phrase should be dropped. Be consistent in reference to the period – you haven't used this elsewhere in referring to the period.

Commented [A21]: Any reason this modifies mfr of a new chemical but not mfr and processing for a SNU later in the subparagraph?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(B) the Administrator shall make public a statement of the finding of the Administrator; and

"(C) the Administrator shall submit the statement described in subparagraph (B) for publication in the Federal Register as soon as is practicable before the expiration of the period for review.

"(2) PUBLICATION.—Publication of a statement in accordance with paragraph (1)(C) is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";

(8) in subsection (h)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "environment," and inserting "environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application;" and

(ii) in subparagraph (B), by striking "appropriate" and inserting "warranted"; and

(B) beginning in the first sentence of paragraph (4), by striking "environment." and all that follows through the "section 6(c)." and inserting "environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use."; and

(9) by striking subsection (i) and inserting the following:

"(i) Definitions.—

"(1) MANUFACTURE; PROCESS.—In this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

"(2) REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.".

Commented [A22]: EPA TA: Did you intend to drop the proviso that this would be without consideration of costs or other nonrisk factors? You included the proviso in the exemption under (h)(4), so there will be a very definite implication here that you intend to have EPA consider cost and non-risk factors when weighing a test marketing exemption application.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 9:31:40 PM
To: McCarthy, David [David.McCarthy@mail.house.gov]; 'Couri, Jerry' [JerryCouri@mail.house.gov]; 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; 'Fruci, Jean' [Jean.Fruci@mail.house.gov]
Subject: HEC TSCA TA Request on section 5
Attachments: HEC.TSCA TA.sec 5 of House (4-22).docx; HEC.TSCA TA.section 5(e) and (f).docx

HEC TSCA Team,
The attached TA documents respond to the request on section 5.

This is in two documents. The first shows, in RLSO, suggested modifications of section 5 as it appears in the House offer (4-22) (e.g., the condensing of 5 findings into 4). The second shows, in RLSO, suggested modifications to section 5(e) and 5(f) of current TSCA; because the House offer (4-22) did not contain the text of these provisions, we could not do the RLSO from that document.

With respect to 5(e) and (f), we made as few changes as we reasonably could to these subsections, but as you will see, the conversion of these from provisions intended to block manufacture and processing into provisions intended to allow manufacturing and processing to proceed with restrictions necessitated the striking of and revision to a fair amount of the text.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 5:20:27 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
Subject: RE: SEPW TSCA TA on nomenclature

Dimitri,
We lined things up for weekend support. I'll continue to be a conduit for the EPA team and will be watching for emails – can also reach my cell at Ex. 6 - Personal Privacy Best wishes on today's session,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, March 11, 2016 12:19 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: SEPW TSCA TA on nomenclature

Thanks for this Sven, very helpful.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 11, 2016 12:13 PM
To: Karakitsos, Dimitri (EPW)
Subject: SEPW TSCA TA on nomenclature

Dimitri, this responds to your TA request on nomenclature. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

1. **Is the Senate nomenclature language, both Class 2 and statutory mixtures, simply codifying EPA's current practice with regards to those substances?**

   EPA interprets section 8(b)(3)(A)(i) as a requirement to continue its current practice of allowing Class 2 chemical substances to be named and listed as discrete entries on the TSCA Inventory. EPA also interprets this provision as allowing EPA to retain technical discretion to ensure that Class 2 chemical naming is done correctly.

   Similarly, EPA interprets section 8(b)(3)(A)(ii) as a requirement to continue its current practice of allowing Class 2 chemical substances to be named according to the SDA nomenclature system. EPA also interprets this provision as allowing EPA to retain technical discretion to ensure that SDA naming is done correctly.

EPA interprets section 8(b)(3)(A)(iii) as a statutory ratification of the scopes of these particular Inventory listings, as listed in the TSCA Inventory, in a manner consistent with appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a). However, the phrase "including, without limitation" could be interpreted to broaden the scope of statutory mixtures currently recognized by EPA. If the intent is to simply codify EPA's current practice, it should be clarified that the list of (I) through (VI) is an exclusive list. Further, while EPA can interpret the phrase "all components of categories that are considered to be statutory mixtures under this Act," the phrasing is awkward and it could be improved to reduce the chance of confusion. The following would be clearer: "all chemical substances described by the following category listings, when manufactured as described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)."

EPA's interpretation of 8(b)(3)(B) is that this provision is wholly inoperative, since EPA is not aware of any "existing guidance" that would trigger 8(b)(3)(B)(i), or duplicate listings on the Inventory that would implicate 8(b)(3)(B)(ii). If this provision is not inoperative, the legislative history in the Senate Committee Report reflects a clear intent that it do something other than merely codify EPA's current practices. Specifically, the Report asserts on page 20 that currently "numerous nomenclature conventions exist that may prevent the efficient distribution of chemicals into commerce," and it explains that the nomenclature provisions "will resolve these issues" by establishing new requirements for EPA. The Report also indicates that the nomenclature provisions will "enable[] similar substances to rely on the Inventory listing of an existing substance." This appears to be a reference to narrowing the scope of substances that will require review under Section 5, due to nomenclature changes.

2. **Is EPA aware of widespread (or any instances) where current Class 2 or statutory mixture language has been abused or used to circumvent Section 5 by allowing entirely new chemicals to market without going through the pmn process?**

EPA has taken a limited number of enforcement actions related to overly broad interpretation of the coverage of Class 2 chemicals on the Inventory. In addition, many manufacturers have sought confirmation from EPA that chemicals they intend to manufacture are covered by Class 2 chemicals on the Inventory and not subject to PMN requirements. In many of these cases, the Agency has responded that PMNs would be required.

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, March 03, 2016 1:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA on nomenclature

Sven – there seems to be continued confusion over the Senate's nomenclature provisions. I know you all are working on a lot for us and we appreciate it but wanted to ask if someone could fairly quickly respond to two specific questions that are designed to be easy answers.

1. Is the Senate nomenclature language, both Class 2 and statutory mixtures, simply codifying EPA's current practice with regards to those substances?
2. Is EPA aware of widespread (or any instances) where current Class 2 or statutory mixture language has been abused or used to circumvent Section 5 by allowing entirely new chemicals to market without going through the pmn process?

Any help with this would be much appreciated.

Thanks,

Dimitri

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 10:32:43 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA additional follow up on section 6/26

Got it- thanks

On Apr 10, 2016, at 6:31 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

ok. thanks. so, given that, I'm planning to move 3. Into 26. The other 2 can't be addressed that way. using House text as your base, I think I need some drafting assistance. I'm afraid that sentence the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure." can't be included.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 4:21 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the followup request on 6/26.

We think there are 3 relevant requirements.

1. the requirement in 6b1 to establish by rule a risk-based screening process

2. the requirement in 6b4B to establish by rule the process for risk evaluations

3. The requirement in 6b4I to issue guidance as to how outside parties can submit their own draft risk evaluations

Please let me know if any questions. Thanks,

Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 10, 2016 at 1:58:35 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA follow up on section 6/26

I understand. I am attaching the Senate's view of what section 6 looks like to resolve this concern for you. it has not yet been sent to the House despite its file name – I am hoping to resolve this section 26 issue before that occurs.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 4:15:06 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - RE deadlines

Michal, this responds to the TA request on RE deadlines.

We are ok with the change.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

On Apr 21, 2016, at 9:36 AM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Michal - got it - checking. Thanks,
Sven

On Apr 21, 2016, at 9:35 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

<!--[if !supportAnnotations]--> <!--[endif]-->
Sven, in the past when I have asked you why the 3 year RE deadline was needed (as opposed to a shorter one) you've told me the following:

Response: The three year timeline for risk evaluation developed from EPA's experience with conducting risk assessments under current TSCA. Given that the scope of assessments under the Senate bill would include all uses of a chemical – and that our current assessments are more limited in scope – reducing the timeframe would likely endanger EPA's ability to meet the timeline.

Section 6 currently provides EPA with the authority to extend the 3 year deadline for completing an RE by one year under specific circumstances. I would like your views on whether the following change would be problematic for you. I note that the effect of this change would be to shorten pause preemption from lasting 2.5-3.5 years to lasting 2.5-3 years.

> Section 6 (b)(4)(G)
>
> "(G) DEADLINES.—The Administrator—
>
> "(i) shall conduct and publish a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates a risk evaluation under paragraphs (2)(A), (1)(B)(i) and (4)(C)(ii); and.
>
> "(ii) may extend the deadline for a risk evaluation for not more than 180 days<!--[if !supportAnnotations]-->[MF1]<!--[endif]--> , if information relating to the chemical substance required to be developed in a rule, order, or consent agreement under section 4 has not yet been submitted to the Administrator, or if such information has been submitted to the Administrator within the time specified in the rule, order or consent agreement and on or after the date that is 120 days before the expiration of the deadline described in clause (i).

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

<!--[if !supportAnnotations]-->

<!--[endif]-->

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/16/2016 2:53:49 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Udall TSCA TA request on section 26

Got it- checking

On Mar 16, 2016, at 10:52 AM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Would like to check with you on the impact of making these changes to the Senate offer...

26(b)(4) do the following:

- Include such amounts as are deposited in the Fund under this paragraph with (4)(A)
- Strike (4)(A)(ii) and (iii)
- Strike (B)(ii)(III) [I know our intent it to section off TSCA money, but I'm not sure what it means]
- Strike (4)(C)
- Add House passed (b)(3)(e) "Accounting and Auditing"
- We have already taken their "Auditing" language and struck ours.
- They are keeping our "Termination" language

<image001.png>

I can send the same email to everyone including Jason if you would like. I would like to but wanted to send to you first.

Ryan Jackson
Chief of Staff
U.S. Senator James M. Inhofe
205 Russell Senate Office Building
202-224-4721
202-228-1007 facsimile

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 9:20:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on 6(a) -"minimum"

Michal – got it, checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 5:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - 6(a) -"minimum"

> (1) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

A question has arisen about the word "minimum". The word is there in part because of the Wyeth case in which the Supreme Court ruled that a VT failure to warn case was NOT preempted even though the manufacturer complied with an FDA labeling requirement. The court said there was no preemptive conflict between an FDA minimum label and what the VT failure to warn law required. The other issue the word "minimum' addresses is the scenario in which EPA sets a labeling requirement based on incomplete or false information and the people harmed by the chemical involving the inadequate label seek to prove that the company should have done more and knew that this was the case, and bring the complaint under state tort law – "minimum" therefore avoids a regulatory compliance defense so the court's decision is about the merits and not the preemptive effect of the federal label. Just because a company didn't HAVE to include the information on the label doesn't mean that they shouldn't have included it, and doesn't mean that they shouldn't have known that harm could have arisen from the chemical substance, and they shouldn't be able to assert preemption in order to avoid having the case heard.

But concerns with the word 'minimum' have been articulated as a belief that it means that a state could ALWAYS exceed a federal minimum labeling standard. My response to this is that section 18 governs this, not the word "minimum". If the state labeling law is grandfathered, it is grandfathered. If the label is required under a state clean air law, it is excepted from preemption. And if the state requests and receives an 18a waiver, preemption for it is waived. I don't see how the word 'minimum' changes anything about the way section 18 governs what states can do and when.

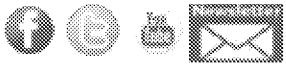
Does EPA agree with my read or am I missing something?

Thanks
michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations

Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 9:39:23 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA on House section 26 (4-22)

Michal- We did not see any new issues raised by the changes they did make. Please let me know if any questions. Thanks,
Sven

On Apr 23, 2016, at 5:26 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just making sure no new issues beyond failure to make requested changes?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 5:13 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA on House section 26 (4-22)

Michal,
This responds to the TA request on section 26 (4-22).

There are few changes from the 4/18 HLC version; the only significant one is the acceptance of the Senate language on scientific standards in 26(h).

We compared the list of changes proposed by the Senate with the version received this afternoon, and have annotated that list to indicate which ones were made and which were not. Most of the proposed changes were not accepted. Among the most significant ones that were not made are the failure to include the language suggested for page 3, lines 2-6, in the Senate list, which was intended to fix the problem in the language saying what fees could be used for, and the failure to delete the phrase "as in effect before such date of enactment" on page 13, line 18, from the end of the provision on moving forward with completed risk assessments, which effectively subjects the yet-to-be completed rule makings on those risk assessments into pre-revision section 6.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/16/2016 7:31:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Request - "unreasonable risk"

thanks

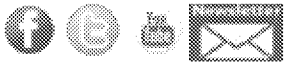
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 16, 2016 2:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Request - "unreasonable risk"

Should be ok

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, February 16, 2016 2:30 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Request - "unreasonable risk"

Michal – Jim has a 4pm, any chance we can push it to 4:30pm? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Tuesday, February 16, 2016 1:58 PM

To: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Re: Request - "unreasonable risk"

Michal - 4 pm on Thurs, Feb 18 works for us. Call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Thanks,
Sven

On Feb 16, 2016, at 12:47 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Call Thursday afternoon sometime btw 2-5?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, February 16, 2016 12:37 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Request - "unreasonable risk"

Michal – we're glad to provide TA in whatever way work best for you and your colleagues. What's your timeframe on getting folks together – I'll check on availabilities. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 16, 2016 12:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Request - "unreasonable risk"

Sven

There's an interest on the part of some (bipartisan) Senate staff to walk through (conference call is fine, so is mtg, so is you sending us a TA document - whatever is best for you) the instances in TSCA where EPA's practice is NOT to consider costs as part of 'unreasonable risk' determinations. The motivation for the question is section 5 exemptions, and whether EPA currently considers costs as part of deciding whether to grant them. We thought it would be useful to go through these statute-wide rather than as they occurred to us.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/1/2016 2:45:17 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on nomenclature

Michal, Got it - thanks. Checking on nomenclature TA and circulating the other questions. Best,
Sven

On Apr 1, 2016, at 10:43 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

A couple of things on nomenclature – first, wondering if you are close to getting the pending nomenclature TA done?

Second, there is a concern being expressed by the House side that the statutory mixture language (even with the modification options I sent you last week) would allow new chemicals to avoid section 5 treatment. What follows below is a draft of a savings clause that would apply to the statutory mixture provisions that is intended to ensure that does not happen. Does it work?

> "Notwithstanding subparagraph (A)(iii), a chemical substance that is a component of a mixture identified in subparagraph (A)(iii) shall be subject to Section 5 when not present in such mixture and if such chemical substance is not included on the list established in paragraph (1)."

Finally, just a general question about class 2 and the Soap and Detergent assoc nomenclature system – how many substances are included on these lists right now? Is EPA contemplating changing these, and if so, what sort of resources would be required to do so? General response is fine on this one.

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 10:56:43 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on PBT - revised draft
Attachments: 04-12-16PBT (Conf Proposal)d.docx; ATT00001.htm

Michal,

This TA responds to the follow up request on PBTs.

We reviewed the attached revised version and still have a difficult time understanding how EPA would be expected to operate under this provision. The language makes clear that for identified PBTs, EPA would propose rules that both protect against unreasonable risks and "reduce exposure to the extent practicable." The language also states that risk evaluations are not required for the identified chemicals. We see the two statements as irreconcilable. EPA determines "unreasonable risk" by doing a risk evaluation on a chemical. Without knowing whether and how the chemical presents an "unreasonable risk," EPA would be unable to draft a rule "in accordance with subsection (a)."

We'd also note that in the absence of risk evaluation under Section 6, there's no associated fee collection authority under Section 26.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 3:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: 04-12-16PBT (Conf Proposal)d.docx

See if this works on pbts

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rule in accordance with subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

(B) exposure to which under the conditions of use is likely to the general population ~~or, to~~ a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Except as provided in paragraph (5), the Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to this subsection.

(3) Final Rule.--Notwithstanding subsections (__), subject to subsections __ and __ , not later than ~~2 years~~18 months after proposing a rule under paragraph (1), the Administrator shall promulgate a rule in accordance with subsection (ae).

(43) In selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a) the Administrator shall, for each chemical substance for which a rule is proposed under paragraph (1), reduce exposure to the substance to the extent practicable.

(54) Relationship to subsection (b).--If, at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (__), or a manufacturer requests a risk evaluation under subsection (__), with respect to a chemical substance, such chemical substance shall not be subject to this subsection, except that any proposed ~~and~~or final rule promulgated in accordance with section 6(a) for such chemical substance shall reduce ~~likely~~ exposure to the extent practicable.

(54) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals

Commented [S1]: X-ref to provision requiring risk management rules on the basis of a risk evaluation

Commented [MF22]: DK: the reference to(c) should be enough for many of these

Commented [S3]: Need to cross-reference language on 50% discount for Work Plans, ensure numerical limitation does not apply, ensure cost-benefit analysis applies to selected risk management measures, and ensure critical use and other exemptions apply PROPOSE FEES FOR EXPOSURE ASSESSMENTS IN FEE PROVISION – AGREE THAT AN INDUSTRY-REQUESTED RE WOULD BE SUBJECT TO FEES AS IS.

Methods Document published by the Administrator in February 2012 (or a successor scoring system) ;and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) that with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) the Administrator shall, in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (ae), reduce exposure to the substance to the extent practicable.

Retain expedited action provision in 6(c)

(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 12:50:55 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Sen. Markey TSCA TA Request following up on Section 4 - exposure monitoring

Michal- this responds to your followup TA request on section 4- exposure assessments. Your option 1 addresses our issue.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 8, 2016 at 5:11:29 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Section 4 - quick q

I don't think I can include the language you suggested that ensures EPA can do testing to monitor exposure. Here are a couple of alternatives:

Protocols and methodologies for the development of information may also be prescribed for the assessment of potential OR ACTUAL exposure to humans or the environment.

Protocols and methodologies for the development of information may also be prescribed for the assessment of OR MONITORING FOR potentiaL exposure to humans or the environment.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 5:19:18 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Weekend coverage

Michal, lots for your group to get through. We lined things up for weekend support. I'll continue to be a conduit for the EPA team and will be watching for emails – can also reach my cell at Ex. 6 - Personal Privacy Thanks,
Sven

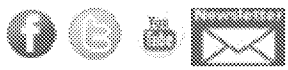
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 11:38 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request - House fees

Was mixed on process, and on substance, we didn't get through much of the more controversial elements – was mostly working through easier sections.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 11, 2016 10:26 AM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA request - House fees

Thanks – how did it go?

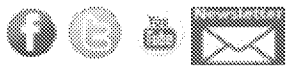
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 10:25 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request - House fees

Yes, or so we were told yesterday.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 11, 2016 10:23 AM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA request - House fees

Michal – we want to make sure we are focusing TA efforts most efficiently – are we right in thinking that it's fees and section 8 today, tomorrow and Sunday will be sections 5 and 6? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 5:05 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Re: Sen. Markey TSCA TA request - House fees

Quick follow up question for you Sven

Would changing "defray the cost of administering the provision for which suhc fee is collected" to

"Defray the cost of administering the provision and any other activities under the act related to the chemical substance or mixture for which such fee is collected" address one of the points you make below?

Would this change above allow you to protect or decide to release CBI that was included in a risk evaluation or test data, for example? Would it allow you to use the results of the test when conducting the risk evaluation or doing risk management?

I recognize that the solution above probably does not address the core resubstantiation obligations provided in the senate bill in section 8. But could it address the question of industry-requested RES and whether the fees for the RE could then be used for rulemaking?

Quick turnaround needed - mtg on this is at 1:30. Feel free to suggest alternatives if what I wrote makes no sense. :-)

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 5:45 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your TA request on House fees language and section 4.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 2:44:56 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Section 6 (4/20) Part 1
Attachments: Markey.TSCA TA.Section 6 (HLC 4-20).Part 1.docx

Michal,
The attached TA responds to the request on section 6 (HLC 4-20). As mentioned in the "highlight points" TA below, the attached TA is the majority of our comments, with TA on PBTs and articles expected to follow later today.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 10:04 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on Section 6 (4/20)

Michal,
This TA responds to the request on section 6 (4-20). Below are initial highlight points. Shortly we will provide RLSO TA on section 6. That will be the majority of our comments, except for TA on PBTs and articles that will follow later today.

- 6(b)(3)(E) -- we see new language from the House that seems to let prioritization deadlines slip in deference to demands for more notice and comment.
- 6(b)(4)(E) -- The denominator to be used in figuring out the min/max of industry requests still seems wrong
- 6(b)(4)(F)(iii) -- To our reading, latest revisions could let in consideration of costs and nonrisk factors if someone argues that they are special costs that are directly related to health and the environment, e.g., Whitman v. American Trucking arguments about health impacts of economic issues.
- 6(d) -- Effective date language mostly (but not entirely) matches our April 11 TA colloquy on this issue. One of the omissions calls into question whether any of the caps on compliance schedules are really hard caps.
- 6(l)(2) -- Stray reference to 6(a) rules being "based on" risk evaluations which could be problematic if not fixed.
- 6(j) -- Low hazard language has all the problems we previously flagged in TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical

assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. ll. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) AMENDMENTS.—Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section heading and inserting "**PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES**";

(2) in subsection (a)—

(A) by striking "finds that there is a reasonable basis to conclude that" and inserting "determines in accordance with subsection (b)(4)(A)";

(B) by inserting "or ~~designates~~that a chemical substance is a substance ~~under~~ described in subsection ~~(b)(4)(A)~~ *section 6PPPPd.(h)*," after "health or the environment,";

(C) by inserting "and subject to section 18, and in accordance with subsection (c)(2)," after "shall by rule";

(D) by striking "to protect adequately against such risk using the least burdensome requirements" and inserting "so that the chemical substance no longer presents such risk";

(E) by inserting "or otherwise restricting" after "prohibiting" in paragraph (2)(A);

(F) by inserting "minimum" before "warnings" both places it appears in paragraph (3);

(G) by striking "and monitor or conduct tests" and inserting "or monitor or conduct tests pursuant to section 4" in paragraph (4); and

(H) in paragraph (7)—

(i) by striking "such unreasonable risk of injury" and inserting "such determination"; and

(ii) by striking "such risk of injury" and inserting "such determination";

(3) by amending subsection (b) to read as follows:

"(b) RISK EVALUATIONS.—

"(1) PRIORITIZATION FOR RISK EVALUATIONS.—

"(A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical

substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or categoriesa category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

Commented [A1]: EPA TA: Responsive to prior EPA TA.

"(B) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

"(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance an active chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment, without consideration of costs or

Commented [A2]: EPA TA: Moving the risk-only proviso closer to the key verb seems helpful.

other nonrisk factors, because of potential hazard

and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

"(ii) LOW-PRIORITY SUBSTANCES.—The Administrator shall designate as a low-priority substance a chemical substance with respect to which the Administrator concludes ~~has~~ based on information sufficient to establish, without consideration of costs or other nonrisk factors, that the chemical substance is not likely to present an unreasonable risk ~~of injury~~ to health or ~~the environment, without consideration of costs or other nonrisk factors,~~ environment under the conditions of use, ~~including~~including an unreasonable risk to a ~~potentially~~potentially exposed or susceptible ~~subpopulation~~ subpopulation identified as relevant by the ~~Administrator~~Administrator.

Commented [A3]: EPA TA: Missing a word here. Sufficient to establish the conclusion.?

Commented [A4]: EPA TA: Responsive to prior EPA TA

"(iii) INACTIVE SUBSTANCES.—The Administrator may designate an inactive chemical substance as a high-priority substance if the Administrator concludes that such substance has not been subject to a regulatory or other enforceable action by

the Administrator to ban or phase out the

substance and has the potential for high hazard and widespread exposure, or has been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substance and with respect to which there exists the potential for residual high hazards ~~or~~and widespread ~~ex-~~posures ~~exposures~~ not otherwise addressed by the regulatory or other action.

Commented [A5]: EPA TA: Standard is now the same, whether or not the substance has been made subject to a ban/phaseout.

"(2) INITIAL RISK EVALUATIONS AND SUBSEQUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) INITIAL RISK EVALUATIONS.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (of which at least 6 shall also be chemical substances that have a Persistence and Bioaccumulation Score of 3).

"(B) ADDITIONAL RISK EVALUATIONS.—

Not later than three and one half years after

the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (of which at least one half shall also be chemical substances that have a Persistence and Bioaccumulation Score of 3).

"(C) CONTINUING DESIGNATIONS AND RISK EVALUATIONS.—The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with subsection (b)(3)(D), subject to the limitation described in subparagraph (B), until all substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (including all such chemical substances that

have a Persistence and Bioaccumulation Score of 3) have undergone risk evaluations and until

Commented [A6]: EPA TA: Prior EPA TA was to replace the "and" with a comma, so that the whole phrase "subject to, [...] have undergone risk evaluations" is set off as a clause. The comma seems to still be missing.

the priority of all active chemical substances has been designated, at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

"(D) PREFERENCE.—In designating high-priority substances, the Administrator shall give preference to—

"(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

"(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

"(E) METALS AND METAL COMPOUNDS.—In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk As-

sessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March

2007 (or a successor document), and may use other applicable information consistent with the best available science.¿

"(3) INFORMATION REQUEST AND REVIEW AND PROPOSED AND FINAL PRIORITIZATION DESIGNATIONS.—

"(A) DEADLINE; PROCESS.—The Administrator shall, in the rulemaking required under paragraph (1)(A), ensure that the time required to make a priority designation of a chemical substance be no longer than 1 year, and that the process for such designations includes—

"(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator is proposing to prioritize;

"(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis and basis used to make the proposed designations,

take public comment on each such proposed designation, and publish all final

designations after the close of the public comment period; and

"(iii) a process by which the Administrator may extend the deadline under this subparagraph for up to six months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

Commented [A7]: x-ref check

"(B) RISK EVALUATION INITIATION.—Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

"(C) REVISION.—The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

"(D) ONGOING DESIGNATIONS.—The Administrator shall designate at least one high-

priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

"(E) PRIORITY DESIGNATION CONSIDERATIONS.—The Administrator shall designate the priority of chemical substances under this subsection at a pace that allows for appropriate notice and comment on each individual chemical substance.

"(4) RISK EVALUATION PROCESS AND DEADLINES.—

"(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

Commented [A8]: EPA TA: This new paragraph weakens the enforceability of the prioritization deadlines and throughput requirements in (b)(2) and (b)(3), by suggesting that they are all subject to adjustment if the Administrator finds that slower pace or throughput is appropriate to accommodate the notice and comment process. Comment periods are usually only on the order of 30-90 days, so it is unclear what concern this is intended to address.

"(B) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

"(C) REQUIREMENT.—The Administrator shall conduct and publish risk evaluations, in

accordance with the rule promulgated under subparagraph (B), for a chemical substance—

"(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

"(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

"(D) SCOPE.—The Administrator shall, as soon as practicable and not later than 6 months after each designation of a high-priority substance, publish the scope of the risk evaluation

Commented [A9]: EPA TA: Change in response to prior EPA TA.

to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider.

"(E) LIMITATION AND CRITERIA.—

"(i) PERCENTAGE REQUIREMENTS.—

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subpara-

Commented [A10]: EPA TA: This is the wrong denominator. You are asking here what % of the EPA-initiated chemicals are industry requests.

We're pretty sure you mean to be asking here what % of the total chemicals (whether EPA-initiated or industry requested) are in fact industry requested.

graph (C), the percentage of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is—

"(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

~~"(II) not more than 50 percent~~50 percent.

"(ii) REQUESTED RISK EVALUATIONS.—Requests for risk evaluations under subparagraph (C)(ii) shall be subject to public notice and comment and to the payment of fees pursuant to section 26(b)(3)(D), and the Administrator shall ~~allocate resources for such risk evaluations consistent with the percentage requirements specified in clause (i) and shall~~ not expedite or otherwise provide special ~~treatment~~treatment to such risk evaluations.

Commented [A11]: EPA TA: Edit responsive to prior EPA TA

"(iii) PREFERENCE.—In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions

imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(iv) EXCEPTIONS.—(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) and that are not drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall not be subject to section 18(b).

"(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

"(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

"(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is rel-

evant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

"(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

~~"(iii) not consider information on cost~~ and costs or other nonrisk factors not directly related to health or the environment;

"(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

Commented [A12]: EPA TA: Prior EPA TA was to conform this to the standard recitation.

"Costs or other nonrisk factors not directly related to health or the environment" is still a non-standard recitation.

As edited, this now suggests that certain costs and certain nonrisk factors **CAN BE** considered, namely, the costs and nonrisk factors that are "directly related to health or the environment."

"(v) describe the weight of the scientific evidence for the identified hazard and exposure.

"(G) DEADLINES.—The Administrator—

"(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates a

risk evaluation under paragraph ~~(1)(B)(i), (2), or~~ (4)(C);

and

"(ii) may extend the deadline for a risk evaluation for not more than 1 year, if information relating to the chemical substance required to be developed in a rule, order, or consent agreement under section 4 has not yet been submitted to the Administrator, or if such information has been submitted to the Administrator within the time specified in the rule, order, or consent agreement and on or after the date that is 120 days before the expiration of the deadline described in clause (i).

"(H) NOTICE AND COMMENT.—The Administrator shall provide no less than 30 days public notice and an opportunity for comment

Commented [A13]: EPA TA: Edits responding to prior EPA TA.

on a draft risk evaluation prior to publishing a final risk evaluation.";

(4) by amending subsection (c) to read as follows:

"(c) PROMULGATION OF SUBSECTION (a) RULES.—

"(1) DEADLINES.—If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment

Commented [A14]: ensuring that conforming changes strike para (3) and (4) of existing TSCA – we know your conforming changes are at the end.

in accordance with subsection (b)(4)(A), the Administrator—

"(A) shall propose and publish in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

"(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

"(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed two years, and subject to the limitation that the Adminis-

Commented [A15]: EPA TA: Edit responsive to EPA TA

trator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan

Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

"(2) REQUIREMENTS FOR RULE.—

"(A) STATEMENT OF EFFECTS.—In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

Commented [A16]: EPA TA: Responsive to prior EPA TA, to align with the later requirement to consider the costs and benefits of the rule, both at the proposal and the final stage.

"(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

"(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

"(iii) the benefits of the chemical substance or mixture for various uses; and

"(iv) the reasonably ascertainable economic consequences of the rule, ~~after consideration~~ including consideration of—

"(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; ~~and~~

"(II) the quantifiable and nonquantifiable costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

"(III) the cost-effectiveness of the proposed regulatory action and of

Commented [A17]: EPA TA: This reverts to current TSCA 6(c), but the structure of current TSCA 6(c) is problematic as a framework to fit in all the issues that follow. For example, effects on the environment and public health are not themselves economic consequences. Also as described below, alternatives analyses are not really analyses of the effects of the actual rule . They are analyses of the effects of the alternative to the rule.

Commented [A18]: EPA TA: The costs and benefits of alternatives considered do not seem relevant to the reasonably ascertainable economic consequences of the rule. These are the rules that didn't get implemented . how can they affect the cost of the rule that did get implemented?

the 1 or more primary alternative regureg-

latoryulatory actions considered by the Ad-

ministrator.

Commented [A19]: EPA TA: Same comment as above, except with respect to cost-effectiveness.

"(B) SELECTING REQUIREMENTS.—In dese-

eiding which requirements to imposelecting among prohibitions and other restric-

tions, the Administrator shall factor in the rulecon-

promulgated in accordance with subsection (a),

the Administrator shall take into consideration,

to the extent practicable, the considerations

siderations under subparagraph (A).

"(C) REPLACEMENT PARTS.—The Admin-

istrator "(i) IN GENERAL.—For complex dura-

ble goods and complex consumer goods, the

Administrator shall exempt replacement

parts ode-

signedthat are designed prior to the effective date of the rule

for articles that are first manufactured prior to

~~the effective date of~~ publication in the ~~Federal~~ Register of the ~~Register of the~~ rule under subsection (a), unless ~~the Ad-~~ ~~ministrator~~ finds that such ~~re-~~ replacement ~~placement~~ parts contribute significantly to the risk ~~the~~ identified in a risk ~~, including evaluation~~ conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture, to the general population or to an identified ~~risk~~ ~~to~~ potentially ~~exposed~~ ~~ex-~~ posed or susceptible ~~sub-~~ subpopulation. ~~populations; or~~

"(ii) DEFINITIONS.—In this subparagraph—

"(I) the ~~replacement part is a compo-~~ term 'complex consumer

~~nent~~ goods' means electronic or mechanical devices composed of 50 manufactured components, with an ~~article that is reasonably ex-~~ intended useful ~~pected to be used by children aged 12~~ life of 3 or more years ~~of age~~, where the product is typically not consumed, destroyed, or discarded after a single use, and ~~younger~~ the components of which would be impracticable to redesign or replace; and

"(II) the term 'complex durable goods' means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

"(D) ARTICLES.—In selecting among ~~pro-~~ hibitions and other restrictions, the ~~—~~ Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or ~~—~~ mixture

only to the extent necessary to address the identified risks from exposure to the chemical

substance or mixture from the article or category of articles, so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

"(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed

in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also—

"(A) publish a notice of proposed rule-making stating with particularity the reason for the proposed rule;

"(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

"(C) promulgate a final rule based on the matter in the rulemaking record; and

"(D) make and publish with the rule the determination described in subsection (a).";

"(4) APPLICATION.—Paragraphs (1), (2), and (3) of this(5) by amending subsection apply(d) to the promulgation—ofread as follows:

"(d) EFFECTIVE DATE.—

Commented [A20]: EPA TA: Deletion of paragraph (4) was responsive to prior EPA TA.

~~"(1) IN GENERAL.—In any~~ rule ~~repealing, or making a substantive amend-~~

~~ment to, a rule promulgated~~ under ~~subsection (a),"; (5) in subsection (d)—~~

~~(A) in paragraph (1), by striking "~~sub-

section ~~(a)~~ the ~~date" and all that follows~~ Administrator shall ~~through "as feasible" and inserting "subsection~~

~~(a)~~

~~"~~(A) specify the date on which it shall take

effect; ~~and~~

"~~(B) dates by~~ which date shall be as soon as practicable;

"(B) except as provided in subparagraph (C), specify mandatory compliance ~~is mandatory dates~~ for all of the requirements under a rule under subsection (a) which

"~~(i)~~ shall be as soon as ~~practicable~~ practicable, but not later than ~~45~~ 10 years after the date ~~of promulgation~~ of promulgation of the rule, except in a case of ~~a use ex-~~ ~~empted~~ a use exempted under subsection (g);

~~"(ii)~~"(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

"(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

"(E) provide for a reasonable ~~transi-~~ transition

tion period, including for restrictions that impose a ban or phase-out of the chemical substance;

"(iii) a period

Commented [A21]: EPA TA: In TA discussions of April 11, this was: "provide for a reasonable transition period, **subject to the compliance dates in subparagraphs (B), (C), and (D)**"

"(2) VARIABILITY.—As determined by the Administrator, the Administrator compliance dates established under paragraph (1) may vary for different affected persons; and per-

~~"(iv) following a determination by the Administrator that compliance is technologically or economically infeasible within the timeframe specified in clause (i), shall provide up to an additional 18 months for compliance to be mandatory~~sons.";~~ and~~

~~(B) in paragraph (2)—~~

~~(i) in subparagraph (A)(i)(I), by inserting ", without consideration of costs or other nonrisk factors" after "such effective date";~~ and

~~(ii) in subparagraph (B)—~~

~~(I) by striking "provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule," and inserting "in accordance with paragraph (3) of subsection (c),"; and~~

~~(II) by striking "; and if such a hearing" and all that follows through "or revoke it";~~

(6) in subsection (e)(4), by striking "paragraphs (2), (3), and (4)" and inserting "paragraph (3)"; and

(7) by adding at the end the following new subsections:

"(g) EXEMPTIONS.—

"(1) CRITERIA FOR EXEMPTION.—The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific use of a chemical substance or mixture, if the Administrator finds that—

"(A) the specific use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

"(B) compliance with the requirement, as applied with respect to the specific use, would significantly disrupt the national economy, national security, or critical infrastructure; or

"(C) the use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(2) EXEMPTION ANALYSIS AND STATEMENT.—In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

~~"(3) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more alternatives to the chemical substance the Administrator determines to be technically and economically feasible and most likely to be used in place~~

of the chemical substance under the conditions of use.

"(4) PERIOD OF EXEMPTION.—The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

"(5) CONDITIONS.—As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the

conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(h) CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC.—~~For a chemical substance subject to~~ "(1) EXPEDITED ACTION.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose rules under subsection (a) ~~that~~ with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments—

"(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation, ~~scores~~ score high for ~~1~~ one and either high or moderate for the other, pursuant to the TSCA Work Plan

Chemicals Methods Document published by the ~~Adminis-~~ ~~trator~~Administrator in February 2012 (or a successor scoring system~~)~~), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4, prior to the date of enactment of the Frank R.

Lautenberg Chemical Safety for the 21st Century Act; and

"(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

"(2) NO RISK EVALUATION REQUIRED.—The Administrator shall, in not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

"(3) FINAL RULE.—Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

"(4) SELECTING RESTRICTIONS.—In selecting among prohibitions and other restrictions, promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce likely exposure to the sub-

225 stancesubstance to the maximum extent practicable.

4

"(5) RELATIONSHIP TO SUBSECTION (B).—If, at any time prior to the date that is 90 days after the date on which the Administrator proposes a rule under paragraph (1) with respect to a chemical substance, the Administrator makes a designation under subsection 6(b)(1)(B)(i), or receives a request under section 6(b)(4)(C)(ii) that meets the criteria prescribed by the Administrator in the rule promulgated under section 6(b)(4)(B), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

"(i) FINAL AGENCY ACTION.—Under this section and subject to section 18—

"(1) a determination by the Administrator that is based on a risk evaluation conducted in accordance with under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the

Commented [A22]: EPA TA: Change responsive to prior EPA TA.

925 order; and

"(2) a final rule promulgated under subsection (a), and the associated determination by the Administrator that is based on a risk evaluation conducted in accordance with subsection (b)(4)(A) on the basis of that a chemical which the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

Commented [A23]: EPA TA: EPA previously flagged the "based on" formulation as potentially supporting an argument that the unreasonable risk determination follows from and is separate from the risk evaluation (and could therefore include cost considerations).

Especially since that issue has been addressed in the paragraph above, a conforming edit should be made here.

We suggest "determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents…"

"(j) CHEMICAL SUBSTANCES CURRENTLY ASSESSED AS LOW-HAZARD.—Not later than one year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall publish a list of not fewer than 25 chemical substances, including uses of a chemical substance identified by the Administrator, that the Administrator has reason to conclude should not be high priorities for risk evaluation under this section because information demonstrates that such chemical substances do not pose a hazard to human health or the environment.

"(k) DEFINITION.—For the purposes of this Act, the term 'requirement' as used in this section shall not displace statutory or common law.".

(b) TABLE OF CONTENTS AMENDMENT.—The item in the table of contents of such Act relating to section 26 is amended to read as follows:

Commented [A24]: EPA TA: EPA notes three issues with this passage:

1) The title says low hazard but the text establishes that the true criterion is no hazard. This may lead to problematic confusion when it is time to implement.

2) EPA doubts that any chemical substance would meet the "do[es] not pose a hazard" standard.

3) No fees are available to defray the cost of responding to industry claims that particular chemical substances are low hazard or no hazard.

"Sec. 5. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.".

Commented [A25]: Not section 6?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 9:45:05 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA DRAFT TA on dates
Attachments: Dates-4.docx; ATT00001.htm

Michal,
This TA responds to the request on dates.

Attached is a draft markup of the language you sent us on dates to accomplish your objectives and which also includes changes aimed at using consistent terminology of "compliance" dates, rather than sometimes implementation and sometimes compliance, and dealing with some grammar issues created by the structure of the previous version. The suggested changes look more significant than they are. We think that the starting point for a ban or phase-out you suggested is reasonable. One last point that we flagged in a comment bubble is that neither what you sent nor what we are sending back establishes an end point for bans or phaseouts.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

(d) EFFECTIVE DATE.—(1) In any rule under subsection (a), the Administrator shall ~~specify~~ :

(A) specify the date on which it shall take effect, which date shall be as soon as feasible;

(B) specify mandatory compliance dates ~~by which full implementation for all~~ of the requirements under a rule under subsection (a) ~~other than requirements for is mandatory, which for requirements that are not~~ a ban or phase-out, which shall be as soon as practicable, but not later than 4 years after the date of promulgation of the rule, except in a case of a use exempted under subsection(g);

(C) specify mandatory compliance dates ~~by which compliance with the~~for the start of ban or phase-out requirements under a rule under subsection (a) ~~is mandatory, which, for requirements in a rule under subsection (a) that are a ban or phase-out,~~ , which shall be as soon as practicable, but not later than 4 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g); and

(D) provide for ~~shall provide for~~ a reasonable transition period~~,~~ , subject to the compliance dates specified in subparagraphs (1)(B) and (1)(C);

~~(E)~~(2) ~~as~~ As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons; ~~and~~.

(3F) Ffollowing a determination by the Administrator that compliance is technologically or economically infeasible within the timeframe specified in subparagraphs (1) (B) or (1)(C), shall provide up to an additional 18 months for compliance to be mandatory.

Commented [GB1]: This is unnecessary though probably not harmful. Subsection (g) exempts a party from whatever requirements EPA issues an exemption for, so it could be confusing to reference (g) in just a subset of section 6 provisions

Commented [GB2]: We note that this establishes no outer bound for full compliance with ban and phaseout requirements.

Commented [GB3]: Same comment about (g)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 11:22:13 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on revised section 14

Michal – got it. We'll take a look and provide TA as requested. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 7:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 14

Sven

Thanks very much for all your rapid assistance today! Attached is a new draft of section 14. Not all changes have been agreed to among Senate offices – some are being discussed or proposed by us, some are raised by the House, etc. But this is at a stage where we would like EPA TA with an eye for concerns related to workability, possible unintended consequences, drafting concerns, inconsistencies, etc. Fast turnaround appreciated.

Thank you
michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 2:22:17 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on closed sections

Michal,
Thanks for sending the closed sections.

We would note that the "closed" Section 3 did not include a definition of "complex durable goods." If that concept is to be included in Section 6, the definition is essential to implementation/workability.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

> On Apr 14, 2016, at 5:07 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Some you have seen some you have not

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 7:23:41 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA - another 6(a) alternative

Michal – got it – checking
Sven

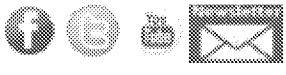
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 3:23 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA - another 6(a) alternative

Thanks. I agree with you that section 18 does not impose a limitation on epa and that any court should be expected to read section 18 if they are being asked to determine whether something has a preemptive effect. The issue with Geier is that MVSA had a tort savings clause in a different section of the bill from the section that created the safety standard in question and that somehow became a 'reading' issue for the courts. If any of those other options work too, or if alternatives exist, pls let me know.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 3:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA - another 6(a) alternative

Michal,
This TA responds to the request to review a 6(a) option dealing with section 18 and (c)(2) references.

OPTION 2

(a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall

by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

The changes you suggest do help address the specific issue we identified in our most recent TA -- the suggestion that section 18 and 6(c)(2) are on the same footing as limitations on EPA's authority. However, it does not address our long standing point that we think the reference to section 18 in this context is unnecessary and confusing. We understand your point about addressing Geier, but we think section 18 already does that (and if it doesn't, it's hard to see how a reference to it in section 6 would). The reference to section 18 in section 6(c) of the offer indicates that EPA's *authority* to promulgate rules under section 6(c) is limited in some way by section 18, which we do not understand to be your intent. Presumably, you mean to say that the *preemptive effect* of any rules EPA promulgates under section 6(c) is subject to section 18. (And, again, we don't really see the value of making such a point in section 6, since section 18 already provides that it governs the preemptive effect of section 6 rules, and has whatever effect it has with respect to Geier.)

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 21, 2016 12:17 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: another 6(a) alternative

OPTION 2

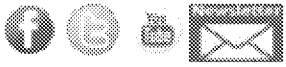
(a) SCOPE OF REGULATION. —If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance does not present such a risk under the conditions of use.:

Does this version address the question you had about why section 18 is there and how it might intersect with a redundant (c)(2) reference? For your context, the subject to section 18 is there to basically address the Geier case, namely that one element of that case involved a court dismissing a state tort action on a car safety matter on preemption grounds despite the existence of a tort savings clause in the motor vehicle safety act.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building

Washington, DC 20510
202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 9:26:55 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Markey TSCA TA on House section 26 (4-22)

Checking - thanks

On Apr 23, 2016, at 5:26 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just making sure no new issues beyond failure to make requested changes?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 5:13 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA on House section 26 (4-22)

Michal,
This responds to the TA request on section 26 (4-22).

There are few changes from the 4/18 HLC version; the only significant one is the acceptance of the Senate language on scientific standards in 26(h).

We compared the list of changes proposed by the Senate with the version received this afternoon, and have annotated that list to indicate which ones were made and which were not. Most of the proposed changes were not accepted. Among the most significant ones that were not made are the failure to include the language suggested for page 3, lines 2-6, in the Senate list, which was intended to fix the problem in the language saying what fees could be used for, and the failure to delete the phrase "as in effect before such date of enactment" on page 13, line 18, from the end of the provision on moving forward with completed risk assessments, which effectively subjects the yet-to-be completed rule makings on those risk assessments into pre-revision section 6.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 3:05:40 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Re: Section 4 - the House offer

Michal - got it. Thanks,
Sven

On Apr 4, 2016, at 11:02 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

I mentioned earlier tonight that the House sent a section 4 offer that I found very concerning. I turned the offer into a redline of tsca in order to illustrate to my colleagues what it would look like.

I don't need detailed TA on this, but would appreciate your high level reaction to it (after section 5, and tomorrow morning is fine).

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<4-04-01-16HOUSESUPPLEMENTALOFFER.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/1/2016 1:08:21 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Section 5 - for review

Michal,
Got it- thanks,
Sven

On Mar 31, 2016, at 8:18 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Attached is new section 5 drafted to existing TSCA. You'll see a number of specific questions we have for you in comments. We have tried to identify all the potential for drafting challenges and deviations from Senate 5 policy – but we are sure you'll find some we missed. Please give this a very careful review for anything you think we may have overlooked, drafted oddly or wrong, etc. There is no intent to meaningfully alter policy here – we are simply shifting into a re-draft using base TSCA in response to a House request that we attempt to do so. Fast turn-around appreciated.

Thanks
Michal
<5-03-31-16-TOEPAv2.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 11:09:09 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA followup Re: Section 4 - exposure monitoring

Michal - good morning. Got it- checking. Thanks,
Sven

On Apr 8, 2016, at 5:11 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I don't think I can include the language you suggested that ensures EPA can do testing to monitor exposure. Here are a couple of alternatives:

Protocols and methodologies for the development of information may also be prescribed for the assessment of potential OR ACTUAL exposure to humans or the environment.

Protocols and methodologies for the development of information may also be prescribed for the assessment of OR MONITORING FOR potentiaL exposure to humans or the environment.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 8:51:02 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on section 5

5:15 works- Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Thanks,
Sven

On Apr 27, 2016, at 4:47 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Could you do 5 pm or 5:15?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 27, 2016 3:57 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 5

Michal,
Availability for a call on the likely/may issue? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 2:03:34 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on Section 6 (4/20)

Michal,
This TA responds to the request on section 6 (4-20). Below are initial highlight points. Shortly we will provide RLSO TA on section 6. That will be the majority of our comments, except for TA on PBTs and articles that will follow later today.

- 6(b)(3)(E) -- we see new language from the House that seems to let prioritization deadlines slip in deference to demands for more notice and comment.
- 6(b)(4)(E) -- The denominator to be used in figuring out the min/max of industry requests still seems wrong
- 6(b)(4)(F)(iii) -- To our reading, latest revisions could let in consideration of costs and nonrisk factors if someone argues that they are special costs that are directly related to health and the environment, e.g., Whitman v. American Trucking arguments about health impacts of economic issues.
- 6(d) -- Effective date language mostly (but not entirely) matches our April 11 TA colloquy on this issue. One of the omissions calls into question whether any of the caps on compliance schedules are really hard caps.
- 6(l)(2) -- Stray reference to 6(a) rules being "based on" risk evaluations which could be problematic if not fixed.
- 6(j) -- Low hazard language has all the problems we previously flagged in TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 8:21:18 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA additional follow up on section 6/26

Michal,
This TA responds to the followup request on 6/26.

We think there are 3 relevant requirements.

1. the requirement in 6b1 to establish by rule a risk-based screening process

2. the requirement in 6b4B to establish by rule the process for risk evaluations

3. The requirement in 6b4I to issue guidance as to how outside parties can submit their own draft risk evaluations

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 10, 2016 at 1:58:35 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA follow up on section 6/26

I understand. I am attaching the Senate's view of what section 6 looks like to resolve this concern for you. it has not yet been sent to the House despite its file name – I am hoping to resolve this section 26 issue before that occurs.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 10:45:33 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Markey TSCA TA request- section 12(a)(2) and (3)

Michal,
This TA responds to your request on sections 12(a)(2) and 12(a)(3).

Previously you noted that the conforming changes to 12(b) were useful. What about the changes to 12(a)(2) or 12(a)(3)? These have been argued to place limitations on existing epa practice/authority.

Response: 12(a)(2) is not placing limitations on existing EPA practice; it is actually expanding EPA's jurisdiction over "export only" chemical substances. Note that under current TSCA, EPA has very limited jurisdiction over chemical substances that are manufactured solely for export. In order to apply the full panoply of TSCA tools to such substances (e.g., essentially anything other than reporting rules under TSCA section 8), EPA must make a preliminary finding under current 12(a)(2) that the substance "will present an unreasonable risk."

The Senate bill clarifies that these unreasonable risk determinations are without consideration of cost or non-risk factors, and it furthermore establishes a more relaxed standard ("likely to present an unreasonable risk") for asserting full TSCA jurisdiction over new chemical substances proposed for export only (12(a)(2)(A)), or the export-only manufacture of existing chemicals that were previously flagged as likely to present an unreasonable risk when they previously came through the new chemicals review process (12(a)(2)(C)). (Note, however, that the cross-reference to section 5(d)(4) is a "broken link" and needs to be updated to reflect the new paragraph structure of the Senate offer.)

The changes to 12(a)(3) could be read as conditioning EPA authority. EPA would not interpret them as imposing a substantive limitation on EPA authority, but they could be read differently. Under TSCA currently, if EPA make the unreasonable risk finding under 12(a)(2) for a chemical, regulation would attach to the chemical itself, and to any mixtures or articles containing the chemical, without any further action or determination. Sec 12(a)(3) adds an additional step before the regulated status of such mixtures and articles is clear. We believe the better reading of the provision would require EPA to make a determination as to such mixtures and articles – such that EPA's only choice is to fully regulate them or regulate them at specified concentrations. However, some might argue that it should be read as giving EPA the discretionary authority to address mixtures and articles, such that if EPA declined to do so in conjunction with a given 12(a)(2) determination, such mixtures and articles would not be regulated under TSCA.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 15, 2016 at 3:01:50 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Cc: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>, "Deveny, Adrian

(Merkley)" <Adrian_Deveny@merkley.senate.gov>
Subject: TA request section 12

Sven

Previously you noted that the conforming changes to 12(b) were useful.

What about the changes to 12(a)(2) or 12(a)(3)? These have been argued to place limitations on existing epa practice/authority.

Thanks
Michal
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 1:06:19 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Sen. Markey TSCA TA Request - section 4 followup

Michal,
This TA responds to the request on section 4.

Wouldn't all testing either be seeking hazard or exposure information? EPA's initial reaction is that this doesn't seem to really narrow the scope of what other authorities can ask for, so it seems harmless.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** April 14, 2016 at 9:40:11 PM EDT
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: RE: Sen. Markey TSCA TA Request - Quick on section 4**
>
> What about the addition of "hazard and exposure"?
>
> Michal Ilana Freedhoff, Ph.D.
>
> Director of Oversight & Investigations
>
> Office of Senator Edward J. Markey
>
> 255 Dirksen Senate Office Building
>
> Washington, DC 20510
>
> 202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 14, 2016 5:00 PM
To: Freedhoff, Michal (Markey)
Subject: FW: Sen. Markey TSCA TA Request - Quick on section 4

Michal,
This TA responds to the request on section 4 adding "federal."

This seems to do what it tries to – limit the requests for developing new information in 4(b)(1)(A)(iv) to requests from federal authorities, whereas they could presumably come from states implementing under a federal law under the language without the insertion of "federal."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 10:53 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick on section 4

This may be too late as I think it was signed off on (by others) but this is a proposed change to section 4. Highlights and brackets note the added text.

this?

‘‘(iv) at the request of the federal implementing authority under another Federal law, to meet the regulatory (hazard and exposure) testing needs of that authority;

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 9:13:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA on House section 26 (4-22)
Attachments: Markey.TSCA TA.House Section 26 (4-22).docx

Michal,
This responds to the TA request on section 26 (4-22).

There are few changes from the 4/18 HLC version; the only significant one is the acceptance of the Senate language on scientific standards in 26(h).

We compared the list of changes proposed by the Senate with the version received this afternoon, and have annotated that list to indicate which ones were made and which were not. Most of the proposed changes were not accepted. Among the most significant ones that were not made are the failure to include the language suggested for page 3, lines 2-6, in the Senate list, which was intended to fix the problem in the language saying what fees could be used for, and the failure to delete the phrase "as in effect before such date of enactment" on page 13, line 18, from the end of the provision on moving forward with completed risk assessments, which effectively subjects the yet-to-be completed rule makings on those risk assessments into pre-revision section 6.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Section 26

Page 1 Line 8: Change to "information" and conform throughout [seems to have been attempted; not sure if done in every instance]

Page 2 Line 9: Strike "such" and insert "the" [not done]

Page 2 Line 23: strike "those" and insert "the" [not done]

Page 3 Line 2-6: strike "to pay or recover the costs incurred by the Environmental Protection Agency in carrying out the provisions of this title for which the fees are collected under" and insert "for use in defraying the costs of the activities described in" [not done]

Page 3 Line 13 strike "subsection" and insert "paragraph (1)" [not done]

Page 6 Line 3: Strike "under section 6(b)(3)(A)(ii) and insert "for chemical substances identified pursuant to section 6(b)(4)(C)(ii)" [changed this cross reference to refer to all risk evaluations under section 6(b)—need to assess implications]

Page 6 Line 8: Strike "(ii)". [not done]

Page 6, Line 14: Insert after "(i)" the following "except as provided in clause (ii)," [not done]

Page 6, Line 16-17; Page 6, Line 23-24; Page 8, Line 10: Reference needs to be to manufacturer risk evaluation under section 6. We think this is 6(b)(4)(C)(ii) based on last draft. [changed cross reference but don't know if done correctly yet]

Page 6, line 20: Strike "section 6" and insert "section 6(b)" [not done]

Page 7, Line 2-3: Strike "annual" [not done]

Page 7, Line 4: Strike "section 6" and insert "section 6(b)" [done]

Page 7, lines 5-8: Strike all after (iii) and insert "apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses". Makes this provision grammatically correct and in the active voice compared to other clauses. [not done]

Page 7, Line 14: Insert after "App.)" the following "or Subchapter II of Chapter 5 of title 5, United States Code" Ensures that the rulemaking will not be considered a negotiated rulemaking. [not done]

Page 9, Line 8 through Page 10 Line 5. Strike (h) on page 9 and accept (h) on page 10. [done]
Page 11, Line 24: Delete "and" [not done]

Page 13, Line 7: Renumber (3) as "(4)" and insert new (3): [not done]

(3) Testing of Chemical Substances and Mixtures.—The policies, procedures, and guidance established under paragraph (1) applicable to testing of chemical substances and mixtures shall —

(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and

(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations.

Page 13, Line 18: Strike "as in effect before such date of enactment." [not done]

Page 14, Line 4: Insert the following at the end: [not done]

(6) NOTICE OF EXISTING INFORMATION.—

(A) IN GENERAL.—The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in risk evaluations with the objective of increasing the efficiency of the risk evaluations.

(B) INCLUSION OF INFORMATION.—Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.

Page 14, Lines 17-18; Page 14, Line 20; Page 14, Line 23: Cross-references need to be checked with section 6 draft. [looks like attempt was made but looks incomplete and don't know if done correctly]

Page 14, Line 19: Strike "to initiate" and insert "to be conducting" [not done]

Page 17, Line 17: Strike "the Frank R. Lautenberg Chemical Safety for the 21st Century Act" and insert "this Act" [not done]

Page 17, Line 23: Strike "this section or section 6" and insert "the Frank R. Lautenberg Chemical Safety for the 21st Century Act." [not done]

Page 18, Line 1: Strike "the Frank R. Lautenberg Chemical Safety for the 21st Century Act" and insert "this Act" [not done]

Page 18, line 6-7: Strike "under subsection (l)" and insert "Frank R. Lautenberg Chemical Safety for the 21st Century Act." [not done]

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 3:03:24 AM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Senate TSCA TA on section 5
Attachments: 5-04-04-16-TOEPAMONDAYNIGHT EPA TA.DOC

Michal,
The attached TA responds to the request on section 5. Note that the RLSO and comments in the side margins might not show up on if reading on a phone. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 04, 2016 8:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: section 5 - for fast turnaround

Sorry this took longer than expected. Please have your team review ASAP, tonight idea.
Michal

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.
Internal x-refs where existing TSCA lettering/numbering changed have not been conformed pending review of text

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsections (b), (e) or (f)); and

(ii) the Administrator conducts a review of the notice and either

(I) makes a determination under paragraph (3)(A) or subsection (g), and, if necessary, takes applicable action required under subsection (f) or

(II) makes a determination under paragraph (3)(B) and issues an order to prohibit or otherwise restrict such manufacturing or processing, any applicable action required under subsections (e) or (f).

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Before the end of the applicable period for review under paragraph (1), and subject to section 18, the Administrator shall review a notice received under paragraph (1) and—

(A) determine ~~whether~~ if the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use,, and take applicable action under subsection (f); or

(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (b)(3).

(4) Failure to Render Determination—

Commented [A1]: Question for EPA: Your TA said that we didn't allow for manufacture even under a subsection (e) situation. Why does this language not work to address that point?

Commented [A2]: EPA TA: Our previous comment was based on the fact that the previous draft required a determination under A prior to manufacture. Under this new drafting, manufacture in a (3)(B) situation can proceed, pending the development of data, so long as EPA issues a 5(e) regulation to govern what manufacturing and processing is allowed in the interim. If EPA makes a (3)(B) determination and doesn't issue a 5(e) order, you revert to a complete ban.

Commented [A3]:

Commented [A4]: EPA TA: This is confusing. As the section is drafted, there is no determination under (g). The determination is under 3A. (g) just specifies the impact of a 3A determination.

Commented [A5]: EPA TA: Not very precise – would be better to say "if required by (f)(1)"

Commented [A6]: EPA TA: Should drop "prohibit or otherwise". Manufacture and processing are prohibited by operation of section 5 following a (B) determination unless EPA issues an (e) order, so there would be no reason for EPA to issue an order to prohibit.

Commented [A7]: EPA TA: Under what provision? (e), right?

Commented [A8]:

Commented [A9]: EPA TA: We continue to think it is confusing and incorrect to suggest that EPA's review of and determination on the notice is subject to the preemption provisions of the bill.

Commented [A10]: Note to EPA – whether or if? Some are thinking that "if" might be more clear

Commented [A11]: EPA TA: "Whether" is preferable – it more clearly indicates the obligation to make a finding one way or another.

Commented [A12]:

(A) In General.—The Administrator shall complete a review of a notice required by this section within the review period provided in subsections (a) and (c).

(B) Failure to Render Determination.—If the Administrator fails to make a determination on a notice under paragraph 3 or under subsection (g) by the end of the applicable review period, including an extension pursuant to subsection (c), the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1).

(C) Limitations.—

(i) A refund of applicable fees under subparagraph (B) shall not be made if the Administrator certifies that the submitter has not provided information required under subsections (b) or (e) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review; and

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule ~~warrants~~justifies notification.

(b) SUBMISSION OF ~~TEST DATA~~INFORMATION.—

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit ~~test data~~information for such substance pursuant to a rule, order or consent agreement ~~promulgated~~ under section 4 before the submission of such notice, such person shall submit to the Administrator such ~~data~~ information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule or order ~~promulgated~~ under section 4 before the submission of such notice,

such person may not, before the expiration of the 90-day period which begins on the date of the submission in accordance with such rule of the ~~test data~~ information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2)(A) If a person—

Commented [A13]: EPA TA: In (a)(3) above it refers to the review period under (1). Should be consistent.

Commented [A14]: EPA TA: Again, there is no determination under (g)

Commented [A15]: Pls review all the new text, and can you confirm that by stating that the notice isn't withdrawn, that also doesn't relieve EPA of its responsibilities to review etc?

Commented [A16]: EPA TA: While (ii) provides an argument that EPA is not relieved of its responsibilities – and that the submitter is not entitled to proceed as if EPA made a favorable determination – it would be clearer if that were specified. Especially since (A) begins with a requirement to complete review within the period, whereas the last draft just provided for refund of fees. A logical place to place this clarification would be at the end of (B).

Commented [A17]:

Commented [A18]: Note to House: the way this was originally drafted in your Section 5 conforming changes, it allows manufacture 90 days after the date the information was required to be submitted, whether the information was submitted or not. Changed back to existing TSCA which keys off the date the information was actually submitted to EPA.

Commented [A19]: EPA TA: Or order, right?

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (5~~4~~), and

(ii) is not required by a rule, order, or consent agreement ~~promulgated~~ under section 4 before the submission of such notice to submit ~~test data~~information for such substance,

such person shall submit to the Administrator ~~data~~ information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information~~Data~~ submitted pursuant to subparagraph (A) shall be information~~data~~ which the person submitting the ~~data~~ information believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) If the Administrator determines under subsection (a)(3)(B) that additional information is necessary to make the determination under subsection (a)(3)(A), the Administrator—

(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

(C) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information;

(D) on receipt of the additional information the Administrator finds supports the determination under subsection (a)(3)(A), shall promptly make the determination; and

(E) may take the actions specified in subsection (e).

(4~~3~~) ~~Data~~ Information submitted under paragraph (1), ~~or~~ (2) or (3) shall be made available, subject to section 14, for examination by interested persons.

(5~~4~~)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those

Commented [A20]: EPA TA: Per earlier TA, we believe it would make sense to specify that the submitter should make the showing without regard to cost or other non-risk factors, but it's probably not critical.

Commented [A21]: Note to EPA: Ultimately we want EPA to make the (a)(3)(A) determination. There are 2 ways manufacture can commence: Make the determination (and get whatever test etc info you need to do that) or issue an order under (e). Why doesn't this work as intended?

Commented [A22]: EPA TA: Our comments on the previous version were based largely on the lack of any possibility of mfr without an a3A determination. Note, though, that this draft still does not require EPA ever to make a determination under a3A.

Commented [A23]:

Commented [A24]: Note to House: per EPA, there could be other factors that go into an unreasonable risk finding and they suggest deleting the limitation on what they can consider, which is why we edited your Section 5 change here.

uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, ~~except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A)~~.

(c) EXTENSION OF NOTICE AND REVIEW PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may, subject to any ~~applicable~~necessary requirements under subsection (e) or (f), begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any ~~test data~~information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information~~data~~ concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information~~data~~ under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or information~~data~~ has been received;

(B) lists the conditions of use of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator ~~s or intended uses of such substance~~; and

(C) in the case of the receipt of information ~~data~~ under subsection (b), describes the nature of the tests performed on such substance and any information ~~data~~ which was developed pursuant

Commented [A25]: EPA TA: The review period here is described as being established under a and b. Earlier it's described as established by a and c, and before that as established by (a)(1). Should be consistent.

Commented [A26]:

Commented [A27]: Note to House- we think the 5 day timeframe is probably a tough timeframe for EPA to have to satisfy the full "conditions of use" definition which is why we have made this change.

to subsection (b) or a rule, order, or consent agreement under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the ~~notification~~ period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such ~~notification~~ period has expired since the last publication in the Federal Register of such list.

(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1)~~(A)~~ If the Administrator determines that—

~~(i)~~ the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) ~~permit a reasoned evaluation of the health and environmental effects of~~ for a chemical substance or significant new use with respect to which notice is required by subsection (a)~~, and~~

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance~~, the Administrator may issue ~~an proposed~~an order to take effect on the expiration of the applicable notification and review period ~~applicable to the manufacturing or processing of such substance~~ under subsection (a), (b), or (c)~~,~~ to prohibit or ~~limit~~ otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of ~~such~~ the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or to prohibit or ~~limit~~ otherwise restrict any combination of such activities, sufficient ~~to~~ address the potential risk of~~so that~~ the chemical substance or significant new use until the Administrator makes the determination in subsection (a)(3)(A). ~~.~~

(2~~B~~) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator under ~~sub~~paragraph (1A), the Administrator shall consider costs and other non-risk factors.

(3~~C~~) If the Administrator issues an order under ~~sub~~paragraph (1A), n~~N~~o person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this paragraph except in compliance with the restrictions specified in ~~the~~such an order ~~issued under subparagraph (A)~~.

(4~~D~~) Not later than 90 days after issuing an order under ~~sub~~paragraph (1A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal

Commented [A28]: EPA TA: Consistency

Commented [A29]: EPA TA: Again, EPA can completely ban interim manufacture simply by not issuing a 5(e) order. This language here is a vestige of the provision of current TSCA that you are significantly re-purposing.

Commented [A30]: EPA TA: "Sufficient to address" is very vague. How about: "sufficient to enable the Administrator to conclude, without consideration of costs or other non-risk factors, that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment"? As we indicated in prior TA, we think this stanard is entirely workable and understandable for judging the safety of a chemical with defined regulatory boundaries on use, even in scenarios where we don't know enough to make an affirmative statement about which side of the "may present an unreasonable risk" line the chemical would sit on if use is unregulated.

Commented [A31]: EPA – thoughts? We find it hard to think about a UR standard in this case which is inherently that EPA doesn't know enough to make such a finding.

Commented [A32]: EPA TA: Nothing in the bill text requires EPA to made an a3A determination.

Commented [A33]: EPA TA: Suggest revising to say "to meet the standard identified in (1)", to be clearer that the cost considerations go to the means, not the end.

Commented [A34]: EPA TA: Should be "the order"

Commented [A35]:

of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) A proposed order may not be issued under subparagraph (1A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

~~(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.~~

~~(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—~~

~~(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or~~

~~(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,~~

~~the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).~~

~~(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.~~

~~(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—~~

~~(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a), and~~

~~(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without~~

Commented [A36]: EPA TA: Why include this? This is designed in TSCA as a protection for the submitter against late hits from EPA, but in this bill, the submitter NEEDS this order to move ahead. Whose interest is this in?

~~consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, or~~

~~(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.~~

~~(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.~~

~~(D) After the submission to the Administrator of information~~test data ~~sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such information~~data by the Administrator, ~~the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.~~

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator ~~finds~~ determines that ~~there is a reasonable basis to conclude that~~ the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may ~~presents or will~~ present an unreasonable risk of injury to health or environment in accordance with subsection (a)(3)(A), ~~before a rule promulgated under section 6 can protect against such risk,~~

(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable notification and review period ~~applicable~~ under subsection (a), (b), or (c) ~~to the manufacturing or processing of such substance, or to the significant new use,~~ to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to protect against such risk ~~for the Administrator to determine that the chemical substance or significant new use is not likely to present such risk take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.~~;

(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a

Commented [A37]: EPA TA: Potential unreasonable risks? (f) is not premised on a positive UR finding.

Commented [A38]:

Commented [A39]: Argument – unreasonable risk already referenced above. OK?

Commented [A40]: EPA TA: Would be better to say: "sufficient to enable the Administrator to conclude, without consideration of costs or other non-risk factors, that the chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment". Even with "such risk", "protect against" is vague. Although (e) and (f) have different on-ramps, conceptually it's hard to see why the objective of regulating would be different.

significant new use pursuant to this subsection except in compliance with the restrictions specified in the order; and

(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the "Administrator for not initiating such a rulemaking.

(2) In selecting among prohibitions and other restrictions to include in aAn order to be issued by Tthe Administrator under paragraph (1) ~~of this subsection or under subsection (e)(1)(A)~~, the Administrator shall consider costs and other non-risk factors, and such an order may include~~issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)~~—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

~~Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.~~

(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A), ~~sufficient to address such risk identified in accordance with subsection (a)(3)(A)~~, reduce potential exposure to the substance to the maximum extent practicable.

(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

~~(3)(A) The Administrator may—~~

~~(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or~~

~~(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the~~

Commented [A41]: EPA TA: Is there some reason (f) has such specificity about the contents of orders, and (e) has none? This comment applies to paragraphs 3 and 4, as well as 2. Again, although e and f have different on ramps, it's not obvious why the discretion as to remedies would differ.

Commented [A42]: EPA TA: "to meet the standard identified in (1)" would be better

Commented [A43]:

Commented [A44]: Note back to EPA: doesn't say you can't consider risk factors. Just says you HAVE to consider costs and non-risk factors.

Commented [A45]: Response to your TA response to first draft – para (2) of Senate offer 6(a) reads as follows. Not sufficient? (2) A requirement—
(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use, (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or (iii) all uses, or
(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use, (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement or (iii) all uses.

Commented [A46]: EPA TA: That should be sufficient. Our comment on the previous version was based on current section 6 factors. Still, it seems more straightforward to simply allow EPA to impose any requirements allowed by section 6, rather than to create a separate A and B, with A containing a portion of 6(a)(1) and B containing 6(a)(2)-(7). Note also, per earlier TA, that we still believe the section 6(a) menu may be constraining, here and in the section 6 context, because it does not authorize EPA in general to restrict or condition manufacture, processing or distribution, short of complete or partial bans.

Commented [A47]:

~~manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.~~

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.~~

~~(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A), and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).~~

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use.~~

(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not justified, then notwithstanding any remaining portion of the period for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of such substance or of such substance for a significant new use, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use, and ~~has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance,~~ the Administrator shall publish a statement of the Administrator's ~~determination~~finding ~~reasons for not initiating such action~~. Such a statement shall be submitted for ~~published~~ publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in

Commented [A48]: EPA TA: This title is wrong and is a vestige of current 5(g), which serves a different purpose. This whole discussion is an integral part of the core 5(a) decisionmaking – it is describing the (a)(3)(A) determination that something doesn't qualify as a "may present". It is not describing a situation where EPA is "not taking action." EPA is taking action because it is making an (a)(3)(A) determination.

Commented [A49]:

Commented [A50]: For EPA: does this work? we want it to head to FR asap but agree we don't want to shorten the review period.

Commented [A51]: EPA TA: This works

accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator for the specific uses identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information ~~data~~ for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

Commented [A52]: Leg counsel to conform internal X-refs here if needed

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information~~data~~ has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information~~data~~ by the applicant on such substance would be duplicative of information~~data~~ which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information ~~data~~ on such substance. No exemption which is granted under this subparagraph with respect to the submission of information~~data~~ for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information~~data~~.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information~~data~~ required under subsection (b)(2) for a chemical substance because of the existence of previously submitted ~~data~~information and if such exemption is granted during the reimbursement period for such information~~data~~, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the information~~data~~ on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b) (2) to submit such information ~~data~~, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall,

after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information ~~data~~ for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such information~~data~~ to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such information~~data,~~

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors. ~~A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).~~ including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator under the conditions of use.

(~~5~~4) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(~~6~~5) Immediately upon receipt of an application under paragraph (1) or (~~5~~4) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) DEFINITIONS.—

(1) For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(2) For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

[15 U.S.C. 2604]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/31/2016 8:28:17 PM
To: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: HEC min TSCA TA request on nomenclature savings clause

Jacqueline – got it. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Thursday, March 31, 2016 4:12 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request

Sven,

I am working on a savings clause that could be added to the nomenclature language in section 8 of the Senate bill to make clear that it only applies to chemical substances on the inventory as of the date of enactment. In other words, a chemical that would be considered new and subject to Section 5 if not for the language will continue to be considered new and subject to section 5. Do I need to distinguish between the various paragraphs in the nomenclature language, or can I treat them all alike for purposes of the savings clause?

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 8:48:42 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on section 5

Checking

On Apr 27, 2016, at 4:47 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Could you do 5 pm or 5:15?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 27, 2016 3:57 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 5

Michal,
Availability for a call on the likely/may issue? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 2:14:14 AM
To: Michal_Freedhoff@markey.senate.gov; dimitri_karakitsos@epw.senate.gov; Adrian_Deveny@merkley.senate.gov; Jonathan_Black@tomudall.senate.gov
Subject: SEPW TSCA TA Request on Section 4
Attachments: 4-04-07-16TOEPA BG.doc; ATT00001.htm

SEPW team,
Attached is the requested TA on section 4.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 07, 2016 1:05 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>
Subject: Sectin 4 - fast turnaround please

There isn't much new here and I tried to clearly mark what was, so you should be able to get through it quickly.

Thanks
Michal

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

Some broad conforming changes for consistency:
Data changed to Information in most places
Standards changed to protocols and methodologies in most places
Some internal and external cross-references not checked (in latter case b/c they depend on decisions to be made in sections 5 and 6)

(a) TESTING REQUIREMENTS.—If the Administrator finds that—

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient ~~data~~ information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such ~~data~~information; ~~or~~

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient ~~data~~ information and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such ~~data~~information; and

(C) testing of a chemical substance is necessary to conduct a risk evaluation under section 6(b); and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule, ~~order, or consent agreement~~ require that testing be conducted on such substance or mixture to develop ~~data~~ information with respect to the health and environmental effects for which there is an insufficiency of ~~data~~ information and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

(3) In addition to the authority provided under paragraphs (1) and (2), the Administrator may, by rule, order, or consent agreement:

(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary –

(i) to review a notice under section 5(d) or to perform a risk evaluation under section 6;

Commented [GB1]: In general, we have commented only on changes and not repeated comments from the previous iteration. That said, we have repeated one or two comments on unchanged text that is closely related to changed text.

Commented [MF2]: Deleted per EPA TA

Commented [GB3]: This formulation, which conforms to the senate bill and offer, does not conform to the formulations in (1) and (2) ("require testing be conducted. . . ."). This may generate questions in the legislative process, and if enacted could give rise to arguments that the scope of (3) is different from that of (1) and (2). That said, EPA is ok with the divergent terminology.

(ii) to implement a requirement imposed in a rule, consent agreement or order issued under section 5(d) or under a rule promulgated under section 6(a);

(iii) pursuant to section 12(a)(4); or

(iv) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

(B) require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitations that

(i) Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, consent agreement or order issued under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance; and

(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

(4) When requiring the development of new information relating to a chemical substance or mixture under paragraph (3), the Administrator shall identify the reasonable basis for concern about the substance or mixture and the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

(5) When requiring the development of new information under this subsection, the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

(b)(1) TESTING REQUIREMENT RULE, ORDER, OR CONSENT AGREEMENT.—A rule, order, or consent agreement under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule, order, or consent agreement,

(B) protocols and methodologies~~standards~~ for the development of ~~test data~~information for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator ~~data~~ information developed in accordance with the protocols and methodologies ~~standards~~ referred to in subparagraph (B).

In determining the ~~standards~~ protocols and methodologies and period to be included, pursuant to subparagraphs (B) and (C), in a rule, order, or

Commented [GB4]: Same point as above.

Commented [GB5]: Per our earlier comments, this introduces a new substantive requirement for testing that does not appear in paragraph (3).

Commented [MF6]: The order authority has to be retained in most of the places where it was taken out unless you don't want the order authority included in the Senate-added provisions to be subject to these requirements

Commented [GB7]: EPA is ok with this

consent agreement under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule, order, or consent agreement. Any such rule, order, or consent agreement may require the submission to the Administrator of preliminary ~~data~~ information during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which ~~standards~~ protocols and methodologies for the development of information ~~test data~~ may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. Protocols and methodologies for the development of information may also be prescribed for the assessment of potential exposure to humans or the environment.

The characteristics of chemical substances and mixtures for which such protocols and methodologies~~standards~~ may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such protocols and methodologies~~standards~~ include epidemiologic studies, serial or ~~hierarchical tiered testing~~tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health. [The Administrator shall reduce the use of animals in the testing of chemical substances or mixtures, to the extent practicable, by taking into consideration existing toxicity information and the availability of validated alternative test protocols that reduce or replace animal tests.]

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the protocols and methodologies~~standards~~ for development of ~~data~~ information prescribed in rules, orders, and consent agreements under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such protocols and methodologies~~standards~~.

(3)(A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph

(B) to conduct tests and submit ~~data~~ information to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such ~~data~~ information on behalf of the persons making the designation.

(~~C~~B) The following persons shall be required to conduct tests and submit ~~data~~ information on a chemical substance or mixture subject to a rule under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

Commented [MF8]: To ensure that testing can assess exposure and not just hazard

Commented [GB9]: This language is helpful, but not as clear as the language we suggested. Per our previous comment, the issue is whether "testing of a chemical substance" includes monitoring for the presence of a chemical substance as well as testing of the chemical substance itself to determine properties of the substance. Your new language could be consistent with the narrower reading. Various physical-chemical properties of a substance (e.g., vapor pressure, solubility) are highly relevant to exposure, and testing for these properties is clearly covered by existing section 4 and the language of this bill, because they are properties of the chemical that can be investigated through standard lab testing of the chemical. So, this language, while giving EPA a strong argument that it can require monitoring, does not foreclose a counter-argument.

Commented [MF10]: Bracketing animal testing language to reflect ongoing discussions

Commented [MF11]: Kept (3) to just rule authority per EPA

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii), with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(4) Any rule, order, or consent agreement under subsection (a) requiring the testing of and submission of ~~data~~ information for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to ~~test data~~information for such substance or mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order or consent agreement under subsection (a) requiring the testing of and submission of ~~data~~ information for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to ~~test data~~information for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, ~~except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall make and publish with the rule the findings described in paragraph (1)(A), (1)(B), or (1)(C), of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.~~

(c) EXEMPTION.—(1) Any person required by a rule or order under sub-section (a) to conduct tests and submit ~~data~~ information on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which ~~data~~ information has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which ~~informationdata~~ are being developed pursuant to such a rule, order or consent agreement a rule under subsection (a) or for which ~~data~~ information is being developed pursuant to such a rule, and

(B) submission of information ~~data~~ by the applicant on such substance or mixture would be duplicative of ~~data~~ information which has been submitted to the Administrator in accordance with such rule, order, or consent agreement or which is being development pursuant to such rule, order, or consent agreement such rule or which is being developed pursuant to such rule,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting ~~data~~ information on such substance or mixture under the rule or order with respect to which such application was submitted.

Commented [MF12]: Deleted per EPA TA and Senate bill

Commented [GB13]: Could delete (5) completely, since it now has no effect. But not a critical issue.

Commented [GB14]: Should be "is"

Commented [GB15]: This is duplicative of preceding newly added text.

Commented [GB16]: duplicative

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit ~~test data~~information on a chemical substance or mixture is granted on the basis of the existence of previously submitted ~~test data~~information and if such exemption is granted during the reimbursement period for such ~~test data~~information (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such ~~test data~~information, for a portion of the costs incurred by such person in complying with the requirement to submit such ~~data~~information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any ~~test data~~information for a chemical substance or mixture is a period—

(i) beginning on the date such ~~data~~ information is submitted in accordance with a rule, order, or consent agreement promulgated under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information ~~test data~~ on a chemical substance or mixture is granted on the basis of the fact that ~~test data~~information is being developed by one or more persons pursuant to a rule, order, or consent agreement promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

Commented [GB17]: "Promulgated" should be deleted. This was deleted in Senate offer.

(i) to each such person who is developing such information~~test data~~, for a portion of the costs incurred by each such person in com-plying with such rule, order, or consent agreement, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying

with such rule, order or consent agreement, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing ~~test data~~information pursuant to a rule~~,~~ order, or consent agreement promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule, order, or consent agreement with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any ~~test data~~information pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such ~~data~~ information in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which ~~data~~ information have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable protocols and methodologies ~~standards~~ for the development of ~~test data~~information; and (3) describe the nature of the ~~test data~~information developed. Except as otherwise provided in section 14, such ~~data~~ information shall be made available by the Administrator for examination by any person.

(e) PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the ~~promulgation of a rule~~development of information under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of ~~data~~ information concerning the effects of the sub-stance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of information~~data~~ upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

Commented [GB18]: Should drop "promulgated"

Commented [GB19]: Need to add "order or consent agreement"

Commented [GB20]: Consent agreement should be dropped here. We understand the logic of this section to be that exemptions can be granted only for rules and orders (since presumably parties who consent won't seek exemptions), but that the exemptions can be granted based on data submitted or to be submitted under rules, orders or consent agreements. Under that logic, this should refer only to rules or orders.

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding[1] sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either issue an order or initiate a rulemaking proceeding under subsection (a), or if such an order is not issued or a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order or initiating such a proceeding.

Commented [MF21]: To ensure EPA can use order authority to respond to ITC recommendations

Commented [GB22]: Could we not proceed through consent agreement?

(2)(A) The committee established by paragraph (1)(A) shall consist of ~~eight~~ ten members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

[1] So in law. Probably should be "preceding".

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of the U.S. Food and Drug Administration from employees of the Administration.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

~~(3) In addition to recommendations made by the committee under paragraph (1), the Administrator shall consider the recommendations of Federal agencies regarding the selection of chemical substances or mixtures for testing under this section.~~

Commented [MF23]: Senate does not believe this text is needed if both ITC and Senate language on federal agency requests is included.

(f) REQUIRED ACTIONS.—Upon the receipt of—

(1) any ~~test data~~information required to be submitted under this Act, or

(2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings ~~from cancer, gene mutations, or birth defects~~, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate ~~appropriate~~ applicable action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, without consideration of costs or other non-risk factors, that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) PETITION FOR ~~STANDARDS~~ PROTOCOLS AND METHODOLOGIES FOR THE DEVELOPMENT OF ~~TEST DATA~~INFORMATION.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) and who is not required under a rule, order, or consent agreement under subsection (a) to conduct tests and submit ~~data~~ information on such substance may petition the Administrator to prescribe ~~standards~~ protocols and methodologies for the development of ~~test data~~information for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such ~~standards~~ protocols and methodologies for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial.

(h) TESTING IN SPECIFIED CIRCUMSTANCES.

(1) IN GENERAL.—The Administrator may by rule, order, or consent agreement require the development of new information relating to a chemical substance or mixture if the Administrator determines that such requirement is necessary—

(A) to carry out section 5(e);

(B) to perform a risk evaluation under section 6(b);

(C) pursuant to section 6(2)(a)(2); or

(D) to make a determination under section 6(b)(3)(A)(i) or under section 6(3)(f).

(2) EXPLANATION OF NEW INFORMATION REQUIREMENTS.—When requiring the development of new information under this subsection, the Administrator shall—

(A) identify the need for such information;

(B) describe how information previously available to the Administrator informed the Administrator's decision to require the development of the new information;

(C) explain the basis for any requirement to use vertebrate animals in such development; and;

(D) require a tiered screening and testing process.

Commented [MF24]: Delete text in lieu of new provisions in 4(a)

[(f) REPORTS ON PROGRESS IN REDUCING THE USE OF ANIMAL TESTING.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 5 years thereafter, the Administrator shall submit to Congress a report that describes the progress made in reducing and replacing animal tests through the use of validated alternative test protocols for assessing risks of injury to health or the environment of chemical substances or mixtures.

(2) INCLUSION.—A report submitted under this subsection shall include information regarding the extent to which testing is conducted using information developed through—

(A) computational toxicology and bioinformatics;

(B) high-throughput screening methods;

(C) testing of categories of chemical substances;

(D) tiered testing methods;

(E) new or revised methods identified by the Interagency Coordinating Committee on the Validation of Alternative Methods; and (F) industry consortia that jointly develop testing data for submission under this title.]

[*Related amendment to section 6: Not later than 90 days after the date on which the Administrator receives information required to be developed under section 4(h)(1)(D), the Administrator shall make the determination under subsection (b)(3)(A)(i) or under subsection f(b)(4)(A)(i) If acting for new section 6 text to address bracketed issues.*]

15 U.S.C. 2603.]

Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the fourth sentence by inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".

Commented [MF25]: Bracketing text to reflect ongoing discussions

Commented [MF26]: Delete text in lieu of new 4(a) provisions

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 4:12:26 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your follow up TA questions regarding the revised fee language.

To protect or decide to release CBI that was included in a risk evaluation or test data?
- Yes

To use the results of the test when conducting the risk evaluation or doing risk management?
- Yes

Industry-requested REs and whether the fees for the RE could then be used for rulemaking?
- Yes

Also, we suggest the following revisions to the fees language to better clarify what chemical substances or mixtures we are talking about. Also the proposition should be "defray the cost . . . **of**" not "for".

"Defray the cost of administering the provision for which such fee is collected and of any other activities under the Act related to the chemical substance or mixture that is the subject of the data submission or risk evaluation ~~for which such fee is collected~~"

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 5:05 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Re: Sen. Markey TSCA TA request - House fees

Quick follow up question for you Sven

Would changing "defray the cost of administering the provision for which suhc fee is collected" to

"Defray the cost of administering the provision and any other activities under the act related to the chemical substance or mixture for which such fee is collected" address one of the points you make below?

Would this change above allow you to protect or decide to release CBI that was included in a risk evaluation or test data, for example? Would it allow you to use the results of the test when conducting the risk evaluation or doing risk management?

I recognize that the solution above probably does not address the core resubstantiation obligations provided in the senate bill in section 8. But could it address the question of industry-requested RES and whether the fees for the RE could then be used for rulemaking?

Quick turnaround needed - mtg on this is at 1:30. Feel free to suggest alternatives if what I wrote makes no sense. :-)

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 5:45 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your TA request on House fees language and section 4.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 11:06:38 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on revised section 26 (WEI16263)

Michal,
Got it- checking. Thanks,
Sven

On Apr 15, 2016, at 6:35 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Can you take a look? If ok, we can have slc conform the current hlc version of the same section. Sometime this AM good.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<redline.doc>
<WEI16263.pdf>
<WEI16263_XML.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 1:36:47 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - RE deadlines

Michal - got it - checking. Thanks,
Sven

On Apr 21, 2016, at 9:35 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

<!--[if !supportAnnotations]--> <!--[endif]-->
Sven, in the past when I have asked you why the 3 year RE deadline was needed (as opposed to a shorter one) you've told me the following:

Response: The three year timeline for risk evaluation developed from EPA's experience with conducting risk assessments under current TSCA. Given that the scope of assessments under the Senate bill would include all uses of a chemical – and that our current assessments are more limited in scope – reducing the timeframe would likely endanger EPA's ability to meet the timeline.

Section 6 currently provides EPA with the authority to extend the 3 year deadline for completing an RE by one year under specific circumstances. I would like your views on whether the following change would be problematic for you. I note that the effect of this change would be to shorten pause preemption from lasting 2.5-3.5 years to lasting 2.5-3 years.

> Section 6 (b)(4)(G)
> "(G) DEADLINES.—The Administrator—
>
> "(i) shall conduct and publish a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates a risk evaluation under paragraphs (2)(A), (1)(B)(i) and (4)(C)(ii); and.
>
> "(ii) may extend the deadline for a risk evaluation for not more than 180 days<!--[if !supportAnnotations]-->[MF1]<!--[endif]--> , if information relating to the chemical substance required to be developed in a rule, order, or consent agreement under section 4 has not yet been submitted to the Administrator, or if such information has been submitted to the Administrator within the time specified in the rule, order or consent agreement and on or after the date that is 120 days before the expiration of the deadline described in clause (i).

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

<!--[if !supportAnnotations]-->

<!--[endif]-->

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 8:38:49 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

We missed the conforming edits- Revising TA on 19. Thanks,
Sven

On Apr 23, 2016, at 4:30 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just verifying before proceeding that you checked conforming edits at the end of the bill?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 4:29 PM
To: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

-- provide for judicial review of test orders under section 19

-- provide for judicial review of rules other than the rules currently enumerated in section 19

-- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 7:10:31 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Cost Consideration Options Chart
Attachments: Markey.TSCA TA.Updated Table on Cost Considerations.3.22.16.docx

Michal – the attached TA responds to the request to update the table of cost consideration options. The new options are labelled "Set A," "Set B," etc. The chart includes some comments in the margin on the new options. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 18, 2016 3:49 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Another TA request on 6(a) rules

Sven

Thanks for the table of alternatives on cost considerations in rulemaking. There was an interest in discussion today in seeing whether there is a way to flip the presumption of the House language in a way that said:

- epa identify remedies that address the unreasonable risk
- from those remedies, then somehow consider costs, whether by using the word cost-effective or some other word.

Can you help w some options (1 or more, however many occur to you), with eye to putting them into that chart? Ideally, I'd like options that fall closer to the Senate side rankings on both analytic burden and litigation risk but which helps the House feel that EPA will not choose the super-expensive unnecessary remedy.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?

2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Cost Considerations in a Rule

- **"S 697"**

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

- **"MERGED HOUSE/SENATE PROPOSAL"**

d) PROMULGATION OF SUBSECTION (b) RULES.

(1) **REQUIREMENTS FOR RULE.—**In promulgating any rule under subsection (b) with respect to a chemical substance or mixture, the Administrator shall factor in the following considerations, and publish a statement describing how they were factored into the rule—

(A) the effects of ~~such~~ **the chemical** substance or mixture on health and the magnitude of the exposure of human beings to **the chemical** ~~such~~ substance or mixture;

(B) the effects of ~~such~~ **the chemical** substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture~~,~~**;**

(C) the benefits of ~~such~~ **the chemical** substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(D)~~)~~ the reasonably ascertainable economic consequences of the rule, after consideration of

(i) ~~after~~ the **likely** effect ~~on~~ **of the rule on** the national economy, small business, technological innovation, the environment, and public health;~~.~~

(ii) the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. ;

(E) any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking. ;

❖ **"SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

❖ **"SUPPLEMENTED SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A) **and shall consider whether the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator under subparagraph (A)(vi) are cost-effective.**

❖ **"H.R. 2576 AS MODIFIED USING EPA TA"**

(B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed population.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

- **"H.R. 2576"**

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risks.

- **SET A from EPA March 21 TA: using the term cost-effectiveness, based on Senate offer structure**

1. Add to 6(c)(2)(A)--

"(vii) the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;"

2. Add the above to 6(C)(2)(A) and add the following at the end of the last sentence of 6(C)(2)(B)—

"and shall generally give preference to requirements that are more cost-effective as determined based on the consideration described in 6(c)(2)(A)(vii)"

- **SET B from EPA March 21 TA: not using the term cost-effectiveness, based on Senate offer structure**

1. Add to 6(c)(2)(A)—

"(vii) the efficiency with which the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator satisfy the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use, as determined in accordance with subsection (b)(4)(A);"

2. Add the above to 6(c)(2)(A) and add the following at the end of the last sentence of 6(c)(2)(B)—

"and shall generally give preference to requirements that are more efficient in satisfying the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use as determined in accordance with subsection (b)(4)(A)"

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

- **SET C from EPA March 21 TA: two versions of revision to House bill language, hewing closest to that language**

  Version 1: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

  Version 2: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective than the other requirements considered by the Administrator, except where the Administrator determines that one or more of the other requirements are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

- **SET D from EPA March 21 TA: more substantial revision to House bill language, to establish a preference rather than a presumption**

  (B) generally give preference to requirements that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
S. 697	**Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Statement describing how analysis was taken into account is already a baseline requirement of administrative law.	**Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified.
Senate Offer	**Second Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces analytical burden.	**Second Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces the range of issues that might be the basis of litigation.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
Merged House/Senate Proposal	**Third Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Requirement to "factor" considerations into a decisions and publish explanatory statement is already a baseline requirement of administrative law. No increase in burden from requirement to "consider and publish a statement"	**Third Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified. Relative to H.R. 2576, list of mandatory factors is more prescriptive, somewhat increasing litigation opportunities to claim EPA failed to consider one of the points.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	Litigation Risk
Supplemented Senate Offer	**Fourth Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added. Overall, there is probably greater analytical burden in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in burden.	**Fourth Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added; Overall, there is probably greater litigation risk in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in litigation risk.
Set D	**Fifth Lowest Analytical Burden Relative to Baseline** The addition of a general preference for more cost-effective options, compared to all the preceding formulations, increases the burden, because EPA would have to develop a record to explain how it overcame the preference in rulemakings where it did so.	**Fifth Lowest Litigation Risk** EPA would have to defend in court any decision to overcome the general preference for more cost-effective options.

Commented [A1]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	Litigation Risk
Set A	**Sixth Lowest Analytical Burden Relative to Baseline** Set D and A seem essentially equivalent in terms of burden. We have ranked Set A as more burdensome because Set A includes a specific requirement to consider the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered in addition to the requirement in both A and D to generally give preference to more cost-effective options. But we do not see that as a meaningful additional requirement in A, and, per the comment attached to the Set D entry, if Set D were placed in a bill that did not as clearly circumscribed EPA's analytic obligation, Set D could be considerably more burdensome than A.	**Sixth Lowest Litigation Risk** EPA would have to demonstrate in court that it considered the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered, and explain any decision to overcome the general preference for more cost-effective options.
Set B	**Seventh Lowest Analytical Burden Relative to Baseline** Close call between A and B, but the substitution of efficiency for cost-effectiveness probably marginally increases the burden as compared by Set A. "Efficiency" is a more general term, so EPA would have to define what it means, and then build a record to show that the standard as defined has been met.	**Seventh Lowest Litigation Risk** The substitution of efficiency for cost-effectiveness probably increases litigation risk as compared by Set A. "Efficiency" is a more general term, so EPA would have to defend its definition of the term and also defend its conclusion that the standard as defined had been met.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
Set C Version 2	**Eighth Lowest Analytical Burden Relative to Baseline** The obligation to impose requirements that are more cost-effective than the other requirements considered, unless EPA determines that other requirements are necessary to ensure no unreasonable risk, imposes a higher record burden on EPA than the preference created in Sets D, A and B. This option expresses cost-effectiveness as a relative concept, in contrast to Set C Version 1, and thereby does not impose an obligation to demonstrate that the selected requirements are cost-effective in some absolute sense. That said, the formulation is best read to require EPA to select the *most* cost-effective of the options it considered, which could require substantial analysis.	**Eighth Lowest Litigation Risk** EPA would have to demonstrate in litigation that it selected the most cost-effective of the requirements considered, or that the selected requirements were necessary to ensure no unreasonable risk – litigation burdens not present in any of the preceding formulations.

Commented [A2]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	Litigation Risk
Set C Version 1	**Ninth Lowest Analytical Burden Relative to Baseline** Similar to Set C Version 2, but EPA would have to define the concept of "cost-effective" used in an absolute sense and develop a record to demonstrate that the selected requirements meet the standard as so defined.	**Ninth Lowest Litigation Risk** Similar to Set C Version 2, but EPA would have to defend its definition of the concept of "cost-effective" used in an absolute sense. Because in EPA's view the term is typically used in a relative sense, there is some concern that the term could be interpreted to mean "cost-beneficial", which is a higher standard in EPA's view than the common understanding of cost-effectiveness. EPA would also have to defend its determination that the selected requirements meet the standard as so defined.

Commented [A3]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	Litigation Risk
H.R. 2576 as modified by EPA TA	**Tenth Lowest Analytical Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces a requirement to determine that the selected option is cost-effective, or, if EPA selects a non-cost-effective option, to determine that there are no protective cost-effective options; but these analytic burdens are bounded by what is practicable based on the information already required to be considered in the rulemaking. Failure to meet the safety standard is clearly a basis to deem an alternative unacceptable. Arguably also implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Tenth Lowest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is some uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary, but this is moderated by the "practicable" language.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	Litigation Risk
H.R. 2576	**Highest Introduced Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces the same analytic objectives as paragraph (B) as modified, but the analysis is less clearly bounded by the information already required to be considered in the rulemaking. Failure to meet the safety standard is very likely a basis to deem an alternative unacceptable. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Highest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/16/2016 5:48:49 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Request - "unreasonable risk"

Checking - thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 16, 2016 12:47 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Request - "unreasonable risk"

Call Thursday afternoon sometime btw 2-5?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, February 16, 2016 12:37 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Request - "unreasonable risk"

Michal – we're glad to provide TA in whatever way work best for you and your colleagues. What's your timeframe on getting folks together – I'll check on availabilities. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 16, 2016 12:28 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Request - "unreasonable risk"

Sven

There's an interest on the part of some (bipartisan) Senate staff to walk through (conference call is fine, so is mtg, so is you sending us a TA document - whatever is best for you) the instances in TSCA where EPA's practice is NOT to consider costs as part of 'unreasonable risk' determinations. The motivation for the question is

section 5 exemptions, and whether EPA currently considers costs as part of deciding whether to grant them. We thought it would be useful to go through these statute-wide rather than as they occurred to us.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 3:31:55 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on section 14 CBI Disclosure Penalties

Michal,
Responding to your followup TA request on CBI penalties.

House section 14(f) creates a prohibition on the use of CBI. Section 14(f) relates back to section 14(a): "No person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection." EPA has not identified any implementation concerns in its own history relating to the scope of the authorized uses of TSCA CBI that are listed under 14(a).

However, because the House bill would amend section 15(1) to allow for enforcement of, *inter alia*, "any requirement of this title", the use restrictions in 14(f) would be enforceable under TSCA section 15 against persons authorized to receive the information, such as states. The substantive effect of this conforming change on the enforceability against unauthorized use and disclosure of information under section 14 may not have been intentional. The potential for imposition of civil and criminal penalties may discourage states, local governments, tribes, and health and environmental professionals from requesting and using CBI for legitimate purposes, for fear of inadvertently using or disclosing the information in a manner not specified, and might be viewed as contrary to other efforts to increase transparency.

This issue could be alleviated by inserting a sentence in revised section 15 stating, "This section does not apply to the disclosure or use of information under section 2613 of this title", or similar language.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, February 26, 2016 11:30 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on section 14 CBI Disclosure Penalties

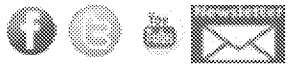
As a follow up, isn't this language in the House bill new? Any workability or other concerns here?

(f) PROHIBITION.—No person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection, nor disclose such information to any person not authorized to receive such information.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey

255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, February 25, 2016 11:52 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 14 CBI Disclosure Penalties

Michal – Please see attached TA responding to your request on TSCA section 14 on CBI. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, February 18, 2016 4:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request section 14

Sven

House section 14 has a penalty provision related to disclosure of CBI.

We are trying to compare this provision with other disclosure penalty provisions that exist in other statutes administered by EPA. We are aware of EPCRA and SDWA provisions, some restrictions on the way RMP data is disclosed, etc., but probably lack a full awareness/understanding of their similarities/differences.

Could you pull the examples of other provisions that create penalties for disclosure of CBI that are included in EPA statutes and give us some basis to compare them with what is in House section 14, along with any problems/limitations/workability concerns that may have been unintended/experienced in those existing statutes? Happy to get any concerns about the way that House provision might be expected to work as well.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 10:13:15 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on SLC section 4
Attachments: Markey.TSCA TA.SLC Section 4 (4-12).docx

Michal,
This TA responds to the request on the SLC version of section 4. Note that the RLSO and comments in the margins might not show up on a phone.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 11, 2016 9:52 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 4

This is the SLC section 4 as redlined by me. some questions in here that I have already asked you but pls look generally, and also see the global comment at the top. Noon tomorrow doable?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. ___. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

GLOBAL COMMENT: Since there is now a subsection (a) and (b) test authority, do some or all of the places where it says subsection (a) be changed to (a) and (b)?

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking "test data" each place it appears and inserting "information";

(2) by striking "data" each place it appears and inserting "information";

(3) in subsection (a)(1)(B)(iii), by striking "and" at the end and inserting "or"; isn't this "or" in current law? In btw (a)(1) and (2) I see "and".

(4) by redesignating subsections (b) through (g) as subsections (c) through (h), respectively;

(5) by inserting after subsection (a) the following:

"(b) Development of New Information.—

"(1) IN GENERAL.—In addition to the authority provided under paragraphs (1) and (2) of subsection (a), the Administrator may, by rule, order, or consent agreement—

"(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

"(i) to review a notice under section 5(d) or to perform a risk evaluation under section 6;

"(ii) to implement a requirement imposed in a rule, consent agreement, or order issued under section 5(e) or 5(f) or under a rule promulgated under section 6(a);

"(iii) pursuant to section 12(a)(4); or

"(iv) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority; and

"(B) require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that the information is necessary to establish the priority of the chemical substance, subject to the limitations that—

"(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, consent agreement, or order issued under this subparagraph, the Administrator shall designate the chemical substance

Commented [A1]: EPA TA: Yes. In any places that section 4 refers to rules, orders or consent agreements, with intent to capture the new (b) authority, reference to (b) needs to be added. For example, current (b)(1) ((new (c)(1)) has been amended to include orders and consent agreements. But the opening language of (b)(1) needs to refer to b as well as a.

Commented [A2]: Have asked EPA

Commented [A3]: EPA TA: It is "and" in current law. There is an "or" after (a)(1)(A)(iii) but an "and" after (a)(1)(B)(iii). We think it should remain an "and". (2) establishes an additional showing that must be made when EPA wants to require testing for mixtues under (a)(1) – it is not a separate basis for testing.

Commented [A4]: Conforms to new 5

Commented [A5]: EPA TA: I don't believe 5e or f contemplaces rules (and not sure about consent agreements)

Commented [A6]: EPA TA: Should be "in"

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

as a high-priority substance or a low-priority substance; and

"(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

"(2) IDENTIFICATIONS REQUIRED.—When requiring the development of new information relating to a chemical substance or mixture under paragraph (1), the Administrator shall—

"(A) identify a reasonable basis for concern about the chemical substance or mixture and the need for the new information;

"(B) describe how information reasonably available to the Administrator was used to inform the decision to require new information;

"(C) explain the basis for any decision that requires the use of vertebrate animals; and

"(D) as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

"(3) TIERED SCREENING AND TESTING PROCESS.—When requiring the development of new information under this subsection, the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

["(4) RELATIONSHIP TO OTHER LAW.—For purposes of this Act, a rule, order, or consent agreement issued under this subsection shall be treated as a rule, order, or consent agreement issued under subsection (a).": [suggested addition to capture applicability of other provisions in TSCA to this new subsection in the same way as the other provisions apply to subsection (a)]]

(6) in subsection (c) (as redesignated by paragraph (4))—

(A) by striking "standards" each place it appears in paragraphs (1) and (2) and inserting "protocols and methodologies";

(B) in paragraph (1)—

(i) in the paragraph heading, by inserting ", ORDER, OR CONSENT AGREEMENT" after "RULE"; and

(ii) by inserting ", order, or consent agreement" after "rule" each place it appears;

(C) in paragraph (2)—

(i) in subparagraph (A)—

Commented [A7]: EPA TA: Note that this deadine may result in a sub-optimal allocation of resources, by putting these chemicals ahead of chemicals with more pressing risk issues.

Commented [A8]: EPA TA: We have pointed out before that this adds a substantive requirement not in (1). It is probably not that high a bar to show a reasonable basis for concern, so we can live with this. But (1) gives EPA authority to require testing to review a section 5 notice or perform a risk evaluation, for example, without requiring a separate demonstration of basis for concern.

Commented [A9]: EPA TA: Suggest changing to "treated in the same manner as a rule under subsection (a)"

Commented [A10]: Running traps w EPA, but subsection (a) doesn't have order or consent agreement authority

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(I) by inserting after the first sentence the following: "Protocols and methodologies for the development of information may also be prescribed for the assessment of potential exposure ~~to humans or the environment.~~"; and

(II) in the last sentence, by striking "hierarchical tests" and inserting "tiered testing"; and

(ii) in subparagraph (B), by inserting ", orders, or consent agreements" after "rules";

(D) in paragraph (4)—

(i) by inserting ", order, or consent agreement" after "Any rule";

(ii) by striking "subsection (c)(3)(B)" and inserting "subsection (d)(3)(B)";

(iii) by inserting "or order or modifies the consent agreement to terminate the requirement" after "repeals the rule";

(iv) by inserting ", order, or consent agreement" after "; and a rule";

(v) by striking "repeals the application of the rule" and inserting "repeals or modifies the application of the rule, order, or consent agreement"; and

(vi) by inserting "or order or modifies the consent agreement to terminate the requirement" before the period at the end; and

(E) in paragraph (5), by striking ", except that" and all that follows through "of such subsection";

(7) in subsection (d) (as redesignated by paragraph (4))—

(A) in paragraph (1), by inserting "or order" after "rule";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "with a rule" and all that follows through "such a rule" and inserting "with a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement";

(ii) in subparagraph (B), by striking "such rule or which is being developed pursuant to such rule" and inserting "such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement"; and

(iii) in the undesignated matter following subparagraph (B), by inserting "or order" after "rule";

(C) in paragraph (3)(B)(i), by inserting ", order, or consent agreement" after "rule"; and

(D) in paragraph (4), by inserting ", order, or consent agreement" after "rule" each place it appears;

Commented [A11]: EPA TA: "Actual" exposure has been dropped from the previous iteration we saw. We believe the language in this draft would give EPA a good argument for requiring monitoring to guage exposure – especially under the new (b) authority – but it leaves the question somewhat open.

Commented [A12]: Need to delete all of paragraph 5

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(8) in subsection (e) (as redesignated by paragraph (4))—

(A) in the first sentence, by inserting ", order, or consent agreement" after "rule"; and

(B) in the second sentence—

(i) by striking "have been received" and inserting "has been received"; and

(ii) by striking "standards" and inserting "protocols and methodologies";

(9) in subsection (f) (as redesignated by paragraph (4))—

(A) in paragraph (1)—

(i) in subparagraph (A), in the first sentence of the matter preceding clause (i), by striking "promulgation of a rule" and inserting "development of information"; and

(ii) in subparagraph (B)—

(I) in the second sentence, by striking "preceeding" and inserting "preceding"; and

(II) in the last sentence—

(aa) by inserting "issue an order or consent agreement" after "either";

Commented [A13]: EPA TA: Need ""or" after agreement

(bb) by striking "or if such" and inserting ", or if such an order or consent agreement is not issued or such"; and

(cc) by inserting "issuing such an order or consent agreement or" after "reason for not"; and

(B) in paragraph (2)(A)—

(i) in the matter preceding clause (i), by striking "eight" and inserting "10"; and

(ii) by adding at the end the following:

"(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

"(x) One member appointed by the Commissioner of Food and Drugs from employees of the Food and Drug Administration.";

(10) in subsection (g) (as redesignated by paragraph (4)), in the first sentence of the undesignated matter following paragraph (2)—

(A) by striking "from cancer, gene mutations, or birth defects";

Strike "data or" in that sentence that includes "such data or information, initiate"

(B) by striking "or information, initiate appropriate" and inserting ", initiate applicable"; and

Commented [A14]: EPA TA: Shouldn't it be "data" not "information" that is stricken here?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

(C) by inserting ", without consideration of costs or other nonrisk factors," after "a finding";

(11) in subsection (h) (as redesignated by paragraph (4))—

(A) in the subsection heading, by striking "Standards for the Development of Test Data" and inserting "Protocols and Methodologies for the Development of Information";

(B) by striking "standards" each place it appears and inserting "protocols and methodologies"; and

(C) in the first sentence, by inserting ", order, or consent agreement" after "rule"; and

(12) by adding at the end the following:

"(i) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures under this Act, by—

"(A) prior to making a request or adopting a requirement for testing using vertebrate animals and in accordance with subsection (b)(2), taking into consideration, as appropriate and to the extent practicable, reasonably available existing information, including—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics; and

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(B) encouraging and facilitating—

"(i) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category; and

"(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the

Commented [A15]: EPA TA: We have commented previously that this section uses both "vertebrate" animals and "animals" raising questions about scope. The apparent intent is to apply to vertebrates. This is a new use of "animal" not in earlier drafts.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

development and implementation of alternative test methods and testing strategies to reduce, refine and replace animal testing for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

"(i) computational toxicology and bioinformatics;

"(ii) high-throughput screening methods;

"(iii) testing of categories of chemical substances;

"(iv) tiered testing methods;

"(v) toxicity pathway-based risk assessments;

"(vi) in vitro studies;

"(vii) systems biology;

"(viii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Cooperation and Development; or

"(ix) industry consortia that develop testing data submitted under this Act;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies, which should be updated on a rolling basis, that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

"(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

"(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods implementation; and

"(F) prioritize and carry out performance assessment, validation, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive

Commented [A16]: EPA TA: Previously this was "or", and it's "or" below in (F).

Commented [A17]: EPA TA: Another example of "animal". There might be a significant difference between developing a plan to reduce vertebrate animal testing and a plan to reduce all animal testing.

Commented [A18]: EPA TA: This language is new. Why try to summarize here the purpose of testing? Not necessarily a big deal.

Commented [A19]: EPA TA: "Animal" point again. Should EPA be considering waivers for non-vertebrate animals?

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the chemical substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(4) VOLUNTARY TESTING.—

"(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability, before conducting new animal testing.

"(B) RELATIONSHIP TO OTHER LAW.—A violation of this paragraph shall not be a prohibited act under section 15.".

(b) Conforming Amendments.—[Once all of the sections are rolled together into 1 draft, need to check the TSCA conforming amendments below against the other section text.]

(1) Section 5(b)(1)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2604(b)(1)(B)(ii)) is amended by striking "section 4(c)" and inserting "section 4(d)".

(2) Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601) is amended by striking "section 4(f)" and inserting "section 4(g)".

Commented [A20]: EPA TA: We note that the Senate bill and offer contained several provisos at this point, including one providing that EPA was not required to review the basis on which a person voluntarily submitting data performed the testing. We think that provision could be useful, in the face of potential arguments that EPA should not use valid animal-based test results it receives if the submitter is in violation of or allegedly in violation of the (A) requirement.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 10:29:14 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Sen. Markey TSCA TA request on revised House section 5 (4-18)

Michal - checking on version. Thanks,
Sven

Begin forwarded message:

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 19, 2016 at 5:11:16 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA request on revised House section 5 (4-18)

Sven - I think you guys might have commented on the 4/12 version not the most recent. Can you pls check? The files are named the same - the time/date stamp is on lower lhs of the page.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Monday, April 18, 2016 9:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on revised House section 5 (4-18)

Michal- the attached TA responds to the request on revised House section 5.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/7/2016 11:28:18 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: SEPW TSCA TA on section 5

Got it - checking

On Apr 7, 2016, at 7:23 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks. quick alternative for you on 5(a). Would this or something like it work? could we then restore the old (b)(3)?

> (i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance, and the Administrator has conducted a review and made a determination under paragraph (3) or subsection (g), and such person complies with any applicable requirement of subsections (b), (e) or (f); and

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 07, 2016 7:03 PM
To: Freedhoff, Michal (Markey)
Cc: Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Re: SEPW TSCA TA on section 5

Section 4 in progress and should follow tonight. Thanks,
Sven

On Apr 7, 2016, at 6:58 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thank you very much

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 07, 2016 6:54 PM
To: Freedhoff, Michal (Markey); Karakitsos, Dimitri (EPW); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: SEPW TSCA TA on section 5

Attached please find the requested TA on the revised section 5.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/2/2016 9:50:46 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall Inquiry on TSCA Section 5

Jonathan – thanks for the request on TSCA Section 5 new chemicals. By specifics, what level of detail are you interested in – do you want the names of the chems? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, November 02, 2016 2:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 5

Hi Sven, I was wondering if you could give me an update on how things are progressing with Section 5 reforms to new chemicals. If possible, it would be helpful to have some specifics about chemicals that are moving forward and some that are not. Thanks.
---Jonathan

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 8:54:51 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA on Section 14(i)

Michal,
Please see TA responding to your request on section 14(i) and CBI claims substantiation limits.

Does this section prevent epa from continuing the CBI reviews (I believe of health and safety mostly) that EPA is currently undertaking? Or just does so after the rules are in effect?

Response: Section 14(i) limits the extent to which EPA can require substantiation or resubstantiation of old CBI claims, but EPA would not read it as limiting the Agency's authority to *review* old CBI claims. While that interpretation could be open to some challenge, EPA believes it is the better interpretation of 14(f) and 14(i) read together.

Even though EPA would not be able to require substantiation in some circumstances under the Senate bill, EPA could nonetheless request substantiation in conjunction with a review and make a determination on the claim whether or not the submitter provides substantiation based on the information in the Agency's possession.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 2:14 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 14(i)

Does this section prevent epa from continuing the CBI reviews (I believe of health and safety mostly) that EPA is currently undertaking? Or just does so after the rules are in effect?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 3:28:23 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA request - House fees

thanks

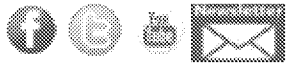
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 10:25 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request - House fees

Oh – and 14 today too

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 11, 2016 10:23 AM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA request - House fees

Michal – we want to make sure we are focusing TA efforts most efficiently – are we right in thinking that it's fees and section 8 today, tomorrow and Sunday will be sections 5 and 6? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 5:05 AM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Re: Sen. Markey TSCA TA request - House fees

Quick follow up question for you Sven

Would changing "defray the cost of administering the provision for which suhc fee is collected" to

"Defray the cost of administering the provision and any other activities under the act related to the chemical substance or mixture for which such fee is collected" address one of the points you make below?

Would this change above allow you to protect or decide to release CBI that was included in a risk evaluation or test data, for example? Would it allow you to use the results of the test when conducting the risk evaluation or doing risk management?

I recognize that the solution above probably does not address the core resubstantiation obligations provided in the senate bill in section 8. But could it address the question of industry-requested RES and whether the fees for the RE could then be used for rulemaking?

Quick turnaround needed - mtg on this is at 1:30. Feel free to suggest alternatives if what I wrote makes no sense. :-)

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 10, 2016 5:45 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request - House fees

Michal,
This responds to your TA request on House fees language and section 4.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 10, 2016 3:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

House fees language basically says that a fee collected under section 4 can only be used for section 4 activities, and so forth. Does EPA have any workability or other concern associated with this provision?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 1:19:07 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen Markey TSCA TA Re: confidential draft

Call on again- we cleared the line. Sorry

On Apr 21, 2016, at 9:16 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I dialed this # but there are people talking about a different topic

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 20, 2016 10:16 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen Markey TSCA TA Re: confidential draft

Michal - that would be great. Let's plan on 9:15 am, let me know if schedule changes. Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Ex. 6 - Personal Privacy Thanks,
Sven

On Apr 20, 2016, at 10:12 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks. Maybe around 9:15?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Wednesday, April 20, 2016 10:01 PM
To: Freedhoff, Michal (Markey)
Subject: Sen Markey TSCA TA Re: confidential draft

Michal,
We went through the narrative points below and would be happy to walk you through our TA. Please let me know best time Thurs morning. In addition we plan to provide TA on the nomenclature, animal testing and section 6 language as soon as possible. Please let me know if any questions. Thanks,
Sven

On Apr 20, 2016, at 6:33 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.
''(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.";

<animal_02_xml.pdf>
<nomenclature with savings.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 2:17:46 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on PBTs - clarification question

Thanks

On Apr 14, 2016, at 10:11 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

yes

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 14, 2016 10:07 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on PBTs - clarification question

Michal,
We have a question on this request.

Is the "exposure assessment" the determination under (X)(1)(B) that "exposure . . . under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator"

Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: April 14, 2016 at 9:46:28 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on PBTs

Something like this

(a) SCOPE OF REGULATION. If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities,

presents an unreasonable risk of injury to health or the environment, [or, for a chemical substance designated under subsection PBT, the risk posed by the substance as evaluated under subsection (exposure assessment)], the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.:

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 14, 2016 5:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on PBTs

TSCA team – please see Michal's request on PBTs. Thoughts? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 5:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Pbts again

Dimitri doesn't like the para 4 and 5 stuff on fixing the unreasonable risk piece. He says can't do a UR finding w"o an RE. Proposes that the text in 6(a) that used to just say "identified under the PBT section" could instead say "or, in the case of a PBT identified in the PBT section, the risk posed by the PBT " or something like that? I am in w them now and can't talk by phone but figured you can start people thinking.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/29/2016 8:45:48 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Udall: With EPA Announcement of First 10 Chemicals for Review Under New Law, Historic Chemical Reform Bill Already Working to Keep Americans Safe

Thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, November 29, 2016 3:45 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Udall: With EPA Announcement of First 10 Chemicals for Review Under New Law, Historic Chemical Reform Bill Already Working to Keep Americans Safe

From: Tom Udall Press Office
Sent: Tuesday, November 29, 2016 3:44 PM
To: Tom Udall Press Office <NEWS_PressOffice@tomudall.senate.gov>
Subject: Udall: With EPA Announcement of First 10 Chemicals for Review Under New Law, Historic Chemical Reform Bill Already Working to Keep Americans Safe

For Immediate Release
November 29, 2016
Contact: Jennifer Talhelm
202.228.6870 | news@tomudall.senate.gov | @SenatorTomUdall

Udall: With EPA Announcement of First 10 Chemicals for Review Under New Law, Historic Chemical Reform Bill Already Working to Keep Americans Safe

WASHINGTON – Today, **U.S. Senator Tom Udall** welcomed the Environmental Protection Agency's (EPA) announcement of the first 10 chemicals that the agency will review for possible risks to public health and the

environment, as required under Udall's Frank R. Lautenberg Chemical Safety for the 21st Century Act. Udall's landmark, bipartisan bill, which was signed into law by President Obama in June, reforms the broken Toxic Substances Control Act of 1976 (TSCA), ensuring that children and communities across the nation are protected from dangerous chemicals.

Udall's bill was the first overhaul of the 1976 TSCA law, a badly broken system that rendered the EPA virtually powerless to regulate the safety of chemicals manufactured and used in commerce. Under the initial TSCA law, tens of thousands of chemicals – including well-documented carcinogens – have been on the market for decades without meaningful regulation or safety evaluation. The EPA's announcement today of the first 10 chemicals it will review complies with the new law's requirement that the EPA release such a list by December 19, 2016.

"I am encouraged by today's news that the EPA has identified the first 10 chemicals for review under the new chemical safety reform law," **Udall said**. "This is one of the first actions required under the reformed law, which was overwhelmingly supported in both houses of Congress and signed by the President in June of this year. It is welcome news that the EPA has listed 10 potentially dangerous chemicals that warrant greater scrutiny for the protection of public health. While there is ample evidence linking these chemicals to cancer and other severe health problems, they have been on the market largely unchecked and unregulated for decades. That's unacceptable, and that is why we worked so tirelessly to reform our broken chemical safety law. Today's action sends a powerful signal to consumers to limit their exposure to chemicals of concern, and to businesses to reduce their use and seek innovative, safer alternatives. Now, we must ensure a seamless transition into the new administration, so that this new chemical safety reform bill can continue to do its job to protect our children and families."

The first 10 chemicals to be evaluated are:

- 1,4-Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster (HBCD)
- Methylene Chloride (MC)
- N-methylpyrrolidone (NMP)
- Pigment Violet 29
- Tetrachloroethylene, also known as perchloroethylene (perc)
- Trichloroethylene (TCE)

The EPA must now complete risk evaluations for the 10 chemicals within three years, and if a chemical is determined to pose a public health or environmental risk, the EPA must take action to mitigate the risk within two years. In the near future, the EPA will designate additional chemicals for safety evaluation.

###

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 8:31:22 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
CC: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Markey TSCA TA on house Section 19 (4-23)

hold on- checking. Thanks

On Apr 23, 2016, at 4:30 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Just verifying before proceeding that you checked conforming edits at the end of the bill?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 23, 2016 4:29 PM
To: Freedhoff, Michal (Markey); Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

-- provide for judicial review of test orders under section 19

-- provide for judicial review of rules other than the rules currently enumerated in section 19

-- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 1:23:34 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Senate TSCA TA on Revised section 4

Michal,
We're having a call on section 5 shortly. Please let me know if anything to tell the team. Thanks,
Sven

On Apr 4, 2016, at 9:01 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thank you very much

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 04, 2016 7:02 PM
To: Freedhoff, Michal (Markey)
Subject: Senate TSCA TA on Revised section 4

Michal,
Please see TA requested on the revised section 4. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 3:23:39 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on section 5 PBTs
Attachments: Markey.TSCA TA.section 5 PBTs.docx

Michal – please see the attached document in response to your TA request on PBTs. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 29, 2016 1:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA PBTs on New Chemicals

Sven:

Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

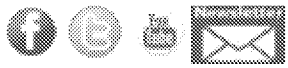
> D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

> D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 7:20 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA PBTs on New Chemicals

Michal,
This responds to your TA request on new chemical reviews. Please let me know if any additional questions
Thanks,
Sven

Question: If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so, and b) how long would scoring take (days, weeks, months, etc?)

a) **Yes, EPA would be able to score new chemicals in the same way it scores chemicals pursuant the TSCA Work Plan Methods document, and**
b) **The time to do so would not extend the PMN process beyond allotted 90-day deadline.**

However, we'd note that application of the New Chemical PBT policy referenced in previous TA is likely to be more stringent than the risk management standard included in the Senate PBT provision - "reduce exposure to the maximum extent practicable"

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBTs

Quick follow up for you – would be great to get this by 5 pm or shortly thereafter. If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so and b) how long would scoring take (days, weeks, months, etc?)

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey

<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 2:04 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBTs

Michal,

This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

EPA currently reviews and categorizes new chemicals for persistence, bioaccumulation, and toxicity (PBT) characteristics under section 5 of TSCA in accordance with a policy statement published in 1999. A copy of the proposed and final policy is available on our website here. New chemicals are not currently scored "pursuant to" the 2012 Work Plan Chemicals Methods document. Because the language in 5(d)(4)(D) does not require a mandatory scoring of new chemicals for P or B pursuant to the Work Plan Chemicals Methods

document, one possible outcome is that EPA never makes such a determination, and the specified risk management standard is never invoked.

EPA United States Environmental Protection Agency

Policy Statement on a New Chemicals Category for ...

On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for Persistent Bioaccumulative and Toxic new chemicals.

Read more...

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between “to the extent practicable” and “to the maximum extent practicable” – the concept of “maximum” seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress’ choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question

Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Question: Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Answer:

We do not think a general direction to take action "consistent with" the referenced policy document would reliably lead to a more stringent outcome than current S. 697, which clearly directs EPA to achieve the more stringent of: (1) What is necessary to meet the safety standard and (2) Exposure reduction to the maximum extent practicable. First, the PBT policy statement at 64 FR 60202 (1999) describes actions that EPA will generally take under section 5 as to PBTs, but it also clearly states that the document provides "general guidance" that is not binding on EPA or outside parties, so EPA could take actions other than the generally recommended control actions that would be consistent with the policy. Second, your draft language references successor policy statements, without circumscribing the content of such statements, so the language ultimately provides little bounding for EPA decisions with respect to new PBT chemicals. Third, since legislative history would reflect that the new language was a change from a strict prior directive to achieve more than the Section 6 safety standard, there would likely be an implication from this revision that Congress intended to allow EPA more flexibility.

You also ask for suggested tweaks, but we would need to better understand your policy objectives, and the perceived deficiencies of the current bill text, to provide language.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 9:27:13 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Quick q section 5(b) - followup

Michal – this responds to the followup quick request on section 5(b)

5(b) is largely preserved from current TSCA, and (as in current TSCA) there is no mechanism for an extension to the review period to allow time for EPA to receive 5(b) information. That's because 5(b) specifies circumstances in which there are heightened requirements for submitting information upfront with the PMN or SNUN. If someone submits a PMN or SNUN that fails to include information required under 5(b), EPA would simply reject the notice as incomplete and the 90 days wouldn't even begin to run.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 3:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Quick q section 5

How could we ensure that any extension associated with a 5(b) requirement to provide data be accounted for as an exception to the 90 day period after the notice is received? Can you suggest something for 5(a)(3)? Fast turnaround appreciated. I think we have something like this in 5(e) that is tied to receipt of the information – could that work? we don't want an automatic 90 day extension, we want to be sure that epa is not forced to make a decision w/o the info it needs or w/o enough time to review it,
Thanks

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 12, 2016 3:18 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Quick q section 5

Michal,
This responds to the TA request on the extension review.

We agree that it is helpful to clarify in 5(a)(3) that the 90 day review period is subject to extension under (c) and (e). But this text goes further, and introduces a further concept that the review period is automatically extended by 90 days upon receipt of information under (b) or (e). There does not appear to be such a provision currently under Section 5, so this is a substantive change, not just accounting for the fact that the 90 day review period can be extended under (c) or (e).

If you just wanted to clarify the status quo, you could say: "(3) Within 90 days of receipt of a notice under paragraph (1), and subject to any extensions of such review period pursuant to subsection (c) or (e), . . ."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 12:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick q section 5

There is a concern that 3(A) lead in does not account for the extension review.

Would this work?

(3) Within 90 days of receipt of a notice under paragraph (1), or of receipt of information submitted pursuant to subsection (b) or (e) that the Administrator finds sufficient to support the determination under subsection (a)(3)A), and subject to any extensions of such review period pursuant to subsection (c) or (e), ~~Before the end of the applicable period for review under paragraph (1),~~ and subject to section 18, the Administrator shall review a notice received under paragraph (1) and— …
?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 6:57:10 PM
To: Richards, Tina [Tina.Richards@mail.house.gov]
CC: Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]; Sarley, Chris [Chris.Sarley@mail.house.gov]
Subject: HEC TSCA TA question on section 14

Tina,
Got it - checking. Please let me know if any additional questions. Thanks,
Sven

On Apr 27, 2016, at 2:44 PM, Richards, Tina <Tina.Richards@mail.house.gov> wrote:

What would be the difference in the burden (cost/time) on the agency if the agency is required to review all CBI to determine whether it still qualifies for protection and then affirmatively make information (that no longer qualifies) available to the public versus just making the information available upon request under FOIA?

Tina Richards
Counsel | Committee on Energy and Commerce
U.S. House of Representatives
259A Ford House Office Building | 202.226.5213 (direct)
<image001.png><image002.png><image003.png><image004.png><image005.png>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 1:23:08 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on Revised House section 19 (4-18)
Attachments: Section 19 Differences between 4.docx; ATT00001.htm

Michal,
The attached TA responds to the request on revised House section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Section 19 Differences between 4/18 HLC version and 4/14 SLC version (page and line numbers refer to 4/18 HLC version)

Page 1, line 6—HLC version says "CERTAIN PRIORITY DESIGNATIONS" while SLC version says "LOW-PRIORITY DESIGNATIONS"

Page 1, line 18—HLC version says "an associated risk evaluation" while SLC version says "the associated determination" [Note: This HLC change appears to conflict with the HLC change on page 4, line 5.](The HLC language on page 1 may have come from an earlier Senate version, but that still leaves what seem to be conflicting changes in the HLC version.)

Page 4, line 4—HLC says "4" while SLC says "4(a)" (Subjects test rules and orders under the new expanded test authority to substantial evidence review, which the Senate bill did not. But probably OK.)

Page 4, line 8—HLC says "4 or" while SLC did not refer to 4 at all (Same comment as above.)

Page 4, lines 17-19—HLC says "including any matter in the record taken as a whole" while SLC says "(including any matter) in the record, taken as a whole"

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/2/2016 1:01:30 PM
To: Bogdanoff, Alec (Markey) [Alec_Bogdanoff@markey.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Request for a Call on Asbestos/PCB TA

Alec – It turns out 3pm works better for us. Ex. 6 - Personal Privacy, code Ex. 6 - Personal Privacy#. I'll send a scheduler. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Tuesday, November 01, 2016 4:48 PM
To: 'Bogdanoff, Alec (Markey)' <Alec_Bogdanoff@markey.senate.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: RE: Request for a Call on Asbestos/PCB TA

Alec - Checking on 2pm tomorrow – will confirm date and time and provide a call in number. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Bogdanoff, Alec (Markey) [mailto:Alec_Bogdanoff@markey.senate.gov]
Sent: Tuesday, November 01, 2016 3:58 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: RE: Request for a Call on Asbestos/PCB TA

Hi Sven,

We are both available from 1:30-4pm tomorrow, and 9-10am & 2:30-5pm on Thursday.

Alec

From: Freedhoff, Michal (Markey)
Sent: Tuesday, November 1, 2016 3:25 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: Re: Request for a Call on Asbestos/PCB TA

Great! Want to suggest times tomorrow afternoon after 1;30 or Thursday (I'm fairly open)? Looping Alec also so he can find a time that works for both of us (I'm out today)

Thanks
Michal
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, November 1, 2016 2:54 PM
To: Freedhoff, Michal (Markey)
Subject: Request for a Call on Asbestos/PCB TA

Michal,
Do you have availability this week for a call to discuss the asbestos/PCB bill TA? Program and OGC folks have some followup questions on the bills that would be easier to handle via discussion.

In addition, I expect today or tomorrow to be able to send you:
- estimated costs and energy savings on light ballast replacement
- TSCA reform implementation questions on conditions of use, first 10 chems, and section 5 and 6 interplay

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/10/2016 6:03:26 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Got it - thanks.

On Apr 10, 2016, at 1:58 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I understand. I am attaching the Senate's view of what section 6 looks like to resolve this concern for you. it has not yet been sent to the House despite its file name – I am hoping to resolve this section 26 issue before that occurs.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 1:54 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA follow up on section 6/26

Michal,
This TA responds to the followup request on section 6/26.

Question 1:
If we move the section 6 guidance for how manufacturers do their own RES to EPA into section 26, have we solved the problem?

Response:

Yes, if that is indeed the only guidance, policy or procedure provision left in sec 6. We note, though, that section 6(b)(8) of the sec 6 version you sent yesterday requires EPA to establish, by rule, a screening process (analogous to 6(b)(1) of the Senate offer). That would likely be viewed as part of the "policies, procedures and guidance" referenced in sec 26(q) that are required to be established. Our previous TA was based on the 3 section 6 guidance provisions you identified yesterday. Also, we note that the section 26(q) provisions allow EPA to proceed with risk evaluation in advance of the 26(k) guidance, but they do not mention screening. To ensure that screening is not held up, it would be best to move 6(b)(8) to 26(k) and add screening to 26(q). We have not thoroughly reviewed the sec 6 you circulated yesterday to see if there are any other provisions we think would likely be viewed as policies, procedures or guidance.

Question 2:

And then I guess associated question is if you're ok w the language in House 26 in this section and the way HLC wrote what used to say "this section"

Response:

We understand that the question refers principally to this text:

Alternate from 4/8/House offer

> Nothing in this Act, or the amendments made by this Act, prevents the Administrator of the Environmental Protection Agency from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator under section 26(k) of the Toxic Substances Control Act, as added by subsection (a) of this section.

If so, this basically looks ok, although it is not clear why "of the EPA" is added after Administrator here and nowhere else. Beyond that, recall that we sent TA yesterday on this version of sec 26, which included TA on this subsection (eg, pointing out that it leaves final risk evaluations, and maybe rules, potentially subject to challenge on the ground that they do not conform with later issued guidance).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)"
<Michal_Freedhoff@markey.senate.gov>
Date: April 10, 2016 at 11:32:18 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

The version you commented on yesterday. If we move the guidance in 6 on industry RES into 26, does that solve the problem and are you ok w the language in the prior initiated RE section if that move is made

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Sunday, April 10, 2016 11:29 AM
To: Freedhoff, Michal (Markey)
Subject: Fwd: Sen. Markey TSCA TA follow up on section 6/26

Michal - we have a version on this. See Brian's question below.
Thanks,
Sven

From: "Grant, Brian" <Grant.Brian@epa.gov>
Date: April 10, 2016 at 11:21:15 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Hey Sven. I don't know what version of the House language she is referring to, with an HLC formulation. Can you please forward to me if you know or ask Michal to forward the version she would like us to look at? thx.
From: "Freedhoff, Michal (Markey)"
<Michal_Freedhoff@markey.senate.gov>
Date: April 10, 2016 at 9:29:57 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

And then I guess associated question is if you're ok w the language in House 26 in this section and the way HLC wrote what used to say "this section"

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:28 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA follow up on section 6/26

Michal- got it- checking. Thanks,
Sven

On Apr 10, 2016, at 9:28 AM, Freedhoff, Michal (Markey)
<Michal_Freedhoff@markey.senate.gov> wrote:

If we move the section 6 guidance for how manufacturers do their own RES to EPA into section 26, have we solved the problem?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 9:24 AM

To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA follow up on section 6/26

Michal,
This TA responds to the request on section 6 and 26.

We'd need to see the full current draft of Section 6 and 26 to give definitive TA, but it seems that (3) is unproblematic. It is not referring to any procedures that EPA needs to develop. Similarly, (4) is unproblematic, assuming that neither (1) nor (2) is referring to policies, procedures, or guidance that EPA needs to develop.

If the language in section 26 is only preserving EPA's ability to proceed in advance of any policies/procedures/guidance developed pursuant to section 26, then the retention of a direction to develop a guidance document pursuant to section 6 (i.e., regarding how outside parties should develop draft risk assessments) is potentially problematic. By specifically not mentioning this guidance document generation obligation, Section 26 could be the basis of an argument that Congress believed that a failure to timely prepare this specific type of guidance document might indeed be grounds to defer work on safety evaluations.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)"
<Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 7:06:01 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)"
<Kaiser.Sven-Erik@epamail.epa.gov>
Subject: follow up on section 6/26

This is the only guidance/policies/practices language that is left in section 6. Is your section 26 Act vs section concern resolved knowing this
GUIDANCE.—
Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator, The guidance shall, at a minimum, address the quality of the information submitted and the process

to be followed in developing draft risk evaluations for consideration by the Administrator.

(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) promulgate a final rule based on the matter in the rulemaking record and (D) make and publish with the rule the determination described in subsection (a).

4) APPLICATION.—Paragraphs (1), (2) and (3) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

<6-04-10-16TOHOUSE.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/15/2016 8:46:11 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: TSCA Reform - heads up on new section 14 coming

Thanks for the heads up - will let folks know.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 4:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request - CBI - 14(c)(4) and 14(d)(1)(D)

TY. As a heads up, we may send you a new section 14 to look at tonight. We'd appreciate rapid turnaround. Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 2:07:20 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on PBTs - clarification question

Michal,
We have a question on this request.

Is the "exposure assessment" the determination under (X)(1)(B) that "exposure . . . under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator"

Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

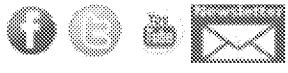
Date: April 14, 2016 at 9:46:28 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on PBTs

Something like this

(a) SCOPE OF REGULATION. If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, [or, for a chemical substance designated under subsection PBT, the risk posed by the substance as evaluated under subsection (exposure assessment)], the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.:

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 14, 2016 5:47 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on PBTs

TSCA team – please see Michal's request on PBTs. Thoughts? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 5:43 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Pbts again

Dimitri doesn't like the para 4 and 5 stuff on fixing the unreasonable risk piece. He says can't do a UR finding w"o an RE. Proposes that the text in 6(a) that used to just say "identified under the PBT section" could instead say "or, in the case of a PBT identified in the PBT section, the risk posed by the PBT " or something like that? I am in w them now and can't talk by phone but figured you can start people thinking.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/23/2016 8:29:24 PM
To: Michal_Freedhoff@markey.senate.gov; Adrian_Deveny@merkley.senate.gov; Jonathan_Black@tomudall.senate.gov
Subject: Sen. Markey TSCA TA on house Section 19 (4-23)

Michal,
While we continue to work on the TA requests on 14 and other sections, we wanted to pass along TA on house section 19 (4-23).

The House discussion draft leaves section 19 from current TSCA un-amended, except for the addition of judicial review of low-priority determinations. Thus, in contrast to the Senate bill and offer, it does not:

-- provide for judicial review of test orders under section 19

-- provide for judicial review of rules other than the rules currently enumerated in section 19

-- provide for judicial review of determinations that a chemical substance does not present unreasonable risk under section 19 (including the substantial evidence review the senate bill and offer would afford).

Note that this does not mean that these EPA actions will not be judicially reviewable. Rather, they would be reviewable in federal district court, rather than the court of appeals, and would be subject to the general federal 6-year review period, rather than the 60 days provided for in section 19.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 2:30:14 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request - cost considerations - pls accelerate response
Attachments: TA on revised cost-effectiveness language 3-1 OGC.docx; ATT00001.htm

Michal,
The attachment responds to your follow up TA request on cost considerations. Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 1, 2016 at 5:39:28 AM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - cost considerations - pls accelerate response

Sven

Attached is a proposal that is similar to option #2 you looked at in that TA document we were discussing yesterday (the one that contained 4 options - option #2 was the one that was incrementally more prescriptive than 697).

It adds cost-effectiveness in a different way - intended not to be as directed as either the option we discussed yesterday or the 2 versions of 2576 that are also in the other TA document.

Does EPA believe this option a) works and b) adds to the analytic burden and litigation risk as compared to old option #2 (and if so, how)?

Quick turnaround appreciated. Thanks.

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Does EPA believe this option a) works

Yes, EPA believes this provision could be implemented. EPA would need to establish whether or not the restrictions in the rule are cost-effective in order to implement "(A) Public Availability," but this analysis would be "under paragraph (1)" and thus bounded by considerations of practicability and reasonably available information. Whether or not the restrictions are found to be cost-effective would control whether EPA has a further duty to include additional descriptive analysis in the administrative record. A key difference with old options ## 3 and 4 relates to whether the necessity discussion is framed as a free-standing determination (as in options ## 3 and 4) or as an integral part of the justification of the proposed rule (as in your draft). Given that the rejection of more direct language on determining cost-effectiveness would be part of the legislative history, Courts would likely construe your proposed text as a signal to give a slightly greater degree of discretion to EPA on the finding (of cost-effectiveness or necessity) than would be afforded under the House bill.

and b) adds to the analytic burden and litigation risk as compared to old option #2 (and if so, how)?

Yes, this language adds to analytic burden relative to old option #2. EPA would need to decide whether the restrictions in the rule were cost-effective, which was not a decision mandated under old option #2. Note also that this language apparently requires EPA to determine whether *each restriction* is cost-effective, not whether the rule as a whole is cost-effective; option #2 in contrast appears to require analysis of the rule as a whole. Furthermore, if a restriction were not cost-effective, EPA would need to develop an analysis of an indeterminate number of alternatives in order to decide whether the restrictions were nonetheless necessary (again, though, bounded by the practicability and reasonable availability limitations).

Yes, this rule adds to the litigation risk relative to old option #2. EPA would need to defend decisions that particular restrictions are cost-effective, or nonetheless necessary, whereas it would not need to do so under old option #2. It is possible, but it cannot be predicted with confidence, that this formulation would entail less litigation risk than old option #3 (i.e., the slightly modified version of House language on cost effectiveness).

Some additional observations:

1. **We note that the inclusion of "mixtures" in this language – which is in TSCA section 6(c) but not in the cost-consideration provisions of either bill – may cause confusion, since section 6 rulemaking under the bills appears to be limited to chemical substances that have been found to present unacceptable risk, not to mixtures per se.**
2. **As the text is reorganized from S 697, (d)(1)(D)(ii) seems awkward, since it is not clear how the costs and benefits of alternative regulatory action would be relevant to the economic consequences of the regulatory action actually selected.**

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/4/2016 11:01:47 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Senate TSCA TA on Revised section 4
Attachments: Section 4 (4-3-16) BG.doc; ATT00001.htm

Michal,
Please see TA requested on the revised section 4. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) TESTING REQUIREMENTS

(1) ~~IN GENERAL.—~~(A) The Administrator may, by rule, order, or consent agreement, require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary –

(i~~A~~) to review a notice under section 5(d) or to perform a risk evaluation under section 6;

(ii~~B~~) to implement a requirement imposed in a rule, consent agreement or order issued under section 5(d) or under a rule promulgated under section 6(a);

(iii~~C~~) pursuant to section 12(a)(4); or

(iv~~D~~) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

(B) The Administrator may, by rule, require that testing be conducted on a chemical substance or mixture to develop information with respect to the health and environmental effects of the chemical substance or mixture if the Administrator finds that the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

(A) IN GENERAL. The Administrator may require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that such information is necessary to establish the priority of the substance..

(B) PRIORITIZATION DECISION BY THE ADMINISTRATOR – Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, consent agreement or order issued under this paragraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance.

(C) LIMITATION: information required by the Administrator under this paragraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

(3) STATEMENT OF NEED – When requiring the development of new information relating to a chemical substance or mixture by issuing an order, the Administrator shall identify the reasonable basis for concern about the substance or mixture and the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, ~~as applicable,~~ explain why issuance of an order is ~~warranted~~justified instead of promulgating a rule or entering into a consent agreement.

Commented [A1]: We are not commenting on cross-references.

Commented [A2]: Suggest starting with "In addition", to make clear that a rule is not required if the testing qualifies under (1)(A), even for chemicals that meet the may present standard.

Commented [A3]: In line with (a)(1), this should probably be: "require the development of information relating to". Otherwise, the implication will be that testing is something narrower (eg, that testing does not include monitoring for exposure).

Commented [A4]: Should probably be "or"

Commented [A5]: Modified from existing TSCA 4(a) to provide rule authority with a 'may present' finding.

Commented [A6]: Picky point, but processing precedes distribution in other TSCA provisions.

Commented [A7]: Specify no consideration of cost and other non-risk factors?

Commented [A8]: The binary choice this gives EPA – to prioritize as high or low within 90 days – might result in a sub-optimal allocation of resources. For example, testing under this provision might indicate that the substance, while not low priority, is also not a high priority compared to other high-priority candidates, but this provision would require EPA to address the tested chemical immediately.

Commented [A9]: Change suggested as result of bicameral discussions noting that if a rule is promulgated, all of this information would be in the rule and subject to notice and comment.

Commented [A10]: This adds a new substantive standard that is not contained in (a)(1). Are the (a)(1) testing bases alone not a sufficient basis to require testing?

Commented [A11]: To address concerns about the word "warranted"

(4) The Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

~~(5) CONSIDERATION OF FEDERAL AGENCY RECOMMENDATIONS.—The Administrator shall consider the recommendations of other Federal agencies regarding the chemical substances and mixtures to which the Administrator shall give priority consideration under this section.~~

Commented [A12]: Incorporating House changes to ITC in lieu of this provision

~~s.—If the Administrator finds that—~~
~~(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,~~
~~(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and~~
~~(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or~~
~~(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,~~
~~(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and~~
~~(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or~~
~~(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;~~
~~the Administrator by rule, require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.~~

(b)(1) TESTING REQUIREMENT RULE, ORDER, OR CONSENT AGREEMENT.—A rule, order, or consent agreement under subsection (a) shall include—

(A) identification of the chemical substance or mixture for

which testing is required under the rule, order, or consent agreement,

(B) test protocols and methodologies ~~standards~~ for the development of test data for such substance or mixture, including specific reference to any reliable non-animal test procedures; and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the ~~standards~~ protocols and methodologies referred to in subparagraph (B).

In determining the ~~standards~~ protocols and methodologies and period to be included, pursuant to subparagraphs (B) and (C), in a rule, order, or consent agreement under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule, order, or consent agreement. Any such rule, order, or consent agreement may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

~~(2)(A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment.~~
~~The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that~~

(2)(A) Before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules, under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(2) The Administrator may require the development of new information by
(A) manufacturers and processors of the chemical substance or mixture;
(B) persons that begin to manufacture or process the chemical substance or mixture after the effective date of the rule, order or consent agreement; or
(C) a qualified third person designated by 2 or more persons identified by the Administrator under subparagraphs (A) or (B), or one of the 2 or more persons so designated.

~~(3)(A) A rule, under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph~~

Commented [A13]: Responding to House Democratic interest in retaining existing statute for this provision.

Commented [A14]: "Standards" should be changed to "protocols and methodologies" throughout, to conform to changes made above. We suggest doing a word search.

Commented [A15]: Responding to House Republican interest in retaining this provision

Commented [A16]: Senate proposes that HLC make surgical changes to existing (3) to remove the test finding references but retain existing statute as much as possible as per House Democratic suggestion.

Commented [A17]: This is garbled. Why require there to be 2 test order recipients before a testing agent is authorized to be designated? And should the second "designated" be "authorized"?

Also, the intent seems to be to allow EPA to directly impose test requirements on third persons. Is that the intent, or is the intent that the mfrs and processors identified in (A) and (B) be able to designate a third party or one among the A and B parties to test, and be able to seek exemptions on that basis? If so, this provision does not seem necessary.

~~(B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.~~

~~(C) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a ruleunder subsection (a):~~

~~(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.~~

~~(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.~~

~~(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.~~

(3) Any rule, order, or consent agreement under subsection (a) requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to test data for such substance or mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order or consent agreement under subsection (a) requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

~~(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.~~

Commented [A18]: Delete in lieu of existing statute above as per House request

~~(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submission, (B) a transcript shall be made of any oral presentation, and (C) the Administrator shall make and publish with the rule the findings described in paragraph (1)(A), or (1)(B) of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.~~

(c) EXEMPTION.—(1) Any person required by a rule or order under sub-section (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and

manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which data are being developed pursuant to such a rule, order or consent agreement ~~a rule under subsection (a) or for which data is being developed pursuant to such a rule~~, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted o the Administrator in accordance with such rule, order, or consent agreement or which is being development pursuant to such rule, order, or consent agreement ~~such rule or which is being developed pursuant to such rule~~,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under the rule or order with respect to which such application was submitted.

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period—

(i) beginning on the date such data is submitted in accordance with a rule, order, or consent agreement ~~promulgated~~ under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule, order, or consent agreement ~~promulgated~~ under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in com-plying with such rule, order, or consent agreement, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, order or consent agreement, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a rule~~,~~, order, or consent agreement ~~promulgated~~ under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule, order, or consent agreement with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any test data pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

[(e) Reduction of Testing on Vertebrates.—

(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

Commented [A19]: Bracketed to reflect ongoing discussions

Commented [A20]: This appears to be taken verbatim from the Senate bill, although we have not read word for word to confirm. Per earlier TA, there is inconsistency in this subsection as to the use of vertebrates and animals. Overall, it seems designed to protect vertebrate animals, but at points is refers more generally to animals.

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, taking into consideration, as appropriate and to the extent practicable, reasonably available—

(i) toxicity information;

(ii) computational toxicology and bioinformatics;

(iii) high-throughput screening methods and the prediction models of those methods; and

(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

(B) encouraging and facilitating—

(i) the use of integrated and tiered testing and assessment strategies;

(ii) the use of best available science in existence on the date on which the test is conducted;

(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

(vi) the submission of information from—

(I) animal-based studies; and

(II) emerging methods and models; and

(C) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

(i) the substance cannot be absorbed; or

(ii) testing for a specific endpoint is technically not practicable to conduct; or

(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

(4) VOLUNTARY TESTING.—

A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop

information using the test methods and testing strategies identified by the Administrator under paragraph (2)(C).]]

(e) PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of data concerning the effects of the sub-stance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, ~~or~~ birth defects or other serious adverse health effects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding[1] sentence, the committee shall make such revisions in the list as it determines to be

Commented [A21]: Retain ITC and include House edits from 4/1/16 draft

Commented [A22]: Section 4(e) as retained here contains exclusive references to testing by rule, and has not been modified to include reference to orders and consent agreements. This could create implementation issues, since, for example, 4(e)(1)(B) requires EPA to initiate rulemaking within 12 months of a chemical's being nominated or explain in the FR why rulemaking has not been initiated.

Commented [A23]: Senate suggestion in lieu of deleting cancer, gene mutations, birth defects

[1] ~~So in law. Probably should be "preceding".~~

necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of ~~eight~~ ten members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of the U.S. Food and Drug Administration from employees of the Administration.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the

90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(3) In addition to recommendations made by the committee under paragraph (1), the Administrator shall consider the recommendations of Federal agencies regarding the selection of chemical substances or mixtures for testing under this section.

Commented [A24]: Note that this gives federal agencies three opportunities to influence testing priorities: under this provision, as part of the ITC, and under 4(a)(1)(A)(iv).

(f) REQUIRED ACTIONS.—Upon the receipt of—

(1) any test data required to be submitted under this Act, or

(2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings ~~from cancer, gene mutations, or birth defects~~, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate ~~appropriate~~ applicable action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, without consideration of costs or other non-risk factors, that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) PETITION FOR STANDARDS FOR THE DEVELOPMENT OF TEST DATA.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(b) and who is not required under a rule, order, or consent agreement under subsection (a) to conduct tests and submit data on such substance may petition the Administrator to prescribe ~~standards~~ protocols and methodologies for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such ~~standards~~ protocols and methodologies for such substance within 75 days of the date the petition is granted. If the petition is denied, the

Commented [A25]: Again, suggest word search to replace this word with protocols and methodologies.

Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial."

Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the fourth sentence by inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/22/2016 5:06:25 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on section 8 - nomenclature
Attachments: Markey.TSCA TA.Nomenclature..docx

Michal,
The attached TA responds to your request about the section 8 nomenclature issues raised by commenters. This TA might help with the section 8 TA request last night. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 6:06 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - nomenclature

Hi Sven

Not sure if your team saw the attached. I would like your views on whether senate 8 would preclude epa requiring PMNS or issuing SNURS for short chain paraffins or nanomaterials as this blog speculates it would. Thanks.

http://switchboard.nrdc.org/blogs/drosenberg/whats_in_that_black_box_inside.html?utm_source=twitterfeed&utm_medium=twitter

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Question:
Not sure if your team saw the attached. I would like your views on whether senate 8 would preclude epa requiring PMNS or issuing SNURS for short chain paraffins or nanomaterials as this blog speculates it would. Thanks.

http://switchboard.nrdc.org/blogs/drosenberg/whats_in_that_black_box_inside.html?utm_source=twitterfeed&utm_medium=twitter

EPA Response:
Commenters on the nomenclature provision have raised some valid points, but they somewhat overstate the scope of the chemical identity issues that are implicated by the nomenclature provisions. The nomenclature provisions relate primarily to Class 2 chemical substances. Overall, EPA would construe the first part of the nomenclature provisions (8(b)(3)(A)) as merely requiring EPA to maintain currently ongoing naming practices with respect to Class 2 chemical substances. With respect to 8(b)(3)(A)(i) and (ii), EPA believes that this would be a strong interpretation.[1] With respect to 8(b)(3)(A)(iii) (statutory mixtures), commenters have a reasonable cause for concern about potential alternative interpretations, as described below.

EPA would construe the second part of the nomenclature provisions (8(b)(3)(B)) as essentially being inoperative because the obligations there are conditioned on circumstances that EPA believes would not arise. However, as with 8(b)(3)(A)(iii), commenters have reasonable cause for concern about potential alternative interpretations.

The Nomenclature Provisions Relate Primarily to Class 2 Substances

At the outset, EPA believes that the issues likely to arise under 8(b)(3) relate more to Class 2 chemical substances than Class I substances. The nomenclature provisions are confusingly drafted and certain portions of them could be the basis of future stakeholder arguments that certain Class 2 chemical substances do not require PMN review, on the grounds that they are or should be treated as already being on the Inventory. Recall that Class 2 chemical substances are named as discrete entries on the Inventory even though they lack a defined molecular structure, whereas Class 1 chemical substances are always identified based on their exact molecular structure. The core concern that seems to be motivating the nomenclature provisions is variation in the composition of a Class 2 chemical substance, and when that variation should result in the treatment of a substance as a new chemical substance. This issue is not always resolvable in terms of "exact molecular structure," for the simple reason that Class 2 chemical substances do not have a single "exact molecular structure."

EPA does not interpret the nomenclature provisions as being equivalently problematic with respect to Class 1 chemical substance (i.e., raising equivalent concerns that EPA should be treating various novel Class 1 chemical substances as being on the Inventory because they are similar in molecular structure to

[1] Some commenters have suggested that a recent TSCA petition (the BRAG petition) may be aligned with these bill provisions. But the BRAG petition asked EPA to *alter* the nomenclature provision addressed in 8(b)(3)(A)(ii) (the Soap and Detergent Nomenclature System). It is thus unclear why the BRAG petition should be viewed as aligned with the purposes of the Senate language. In any event, a requirement to "maintain" a system does not necessarily imply a requirement to freeze the system without alteration.

other Class 1 chemical substances that are on the Inventory). Serious implementation issues would arise if one were to amend the Senate bill so that every chemical substance in commerce needed to be defined in terms of an "exact molecular structure." EPA does not interpret current TSCA as currently requiring every chemical identity to be defined in terms of an exact molecular structure.

Legislative History Supports Commenters' Concerns about Alternative Interpretations

Commenters' characterization of the general objective of the nomenclature provisions (i.e., to reduce the need for PMNs to be filed) appears to be supported by the legislative history in the Senate Report. See, e.g., page 20: "Under TSCA, numerous nomenclature conventions exist. . . . It is the intent of the Committee that the provisions of section [8] related to nomenclature will resolve these issues. . . . The Committee believes this approach will also help enhance EPA's ability to evaluate substances from new sources against existing substances for equivalence, enabling similar substances to rely on the Inventory listing of an existing substance. . . . S. 697 maintains [the] authority [to list chemical substances on the Inventory by category] to ensure that minor modification or variations in the formulation or structure of a chemical substance that have insignificant health or environmental consequences would not be automatically subject to the notification requirements of section 5. The Committee believes that EPA's current policy of not requiring notification for variations in naturally-occurring substances or mixtures should generally be continued."

In general, it has been EPA's approach to list chemicals as precisely as the Agency is able to at the time of listing. It has not been EPA's approach to allow "similar" substances to rely on existing Inventory listings, or to allow substances with minor modifications from listed substances to forego section 5 review. (The Senate Report on page 20 suggests that a value of the nomenclature provisions is that they will help prevent duplicative safety assessments and determinations by ensuring that substantially similar substances are considered at the same time, as appropriate. However, EPA does not see a connection between the nomenclature issues and the safety assessment and determination process, since nothing in the bill prevents EPA from assessing similar but different substances simultaneously.)

This history would tend to undercut an EPA interpretation that the nomenclature provisions have no impact, other than to require continuation of certain long-standing EPA nomenclature practices.

Statutory Mixtures

With respect to the "statutory mixture" provision, 8(b)(3)(A)(ii), the text of the provision does not actually set forth clear directions requiring EPA to depart from prior interpretation of the six listed chemical definitions. The intent behind this provision may be to broaden the scope of chemicals covered under the concept of statutory mixtures, but the effect of the language is difficult to gauge. EPA would probably interpret the language as effecting no change in the implementation of these six listings. But the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six. And the imprecise wording of what is covered even within the six ("treat all components of categories that are considered to be statutory mixtures under this Act") creates the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures. Moreover, even if the identified language were clarified, the argument might be raised, with support from the legislative history referenced above, that this provision was

intended to resolve certain issues, raising questions as to whether EPA's likely interpretation would prevail. Commenters on the bill have noted disputes between EPA and stakeholders about where the bounds of statutory mixtures lie. These disputes are germane, but the bill does not actually have the effect of clearly resolving them.

Arguments that Nomenclature Provisions Might Be Applied to Resolve Various Specific Naming Disputes

Some commenters have expressed concern about how the text of the nomenclature provisions in the Senate bill might be applied to alter the treatment of chlorinated paraffins, nanoscale materials, or micro-organisms under TSCA. EPA cannot predict exactly how the Senate bill language would be applied. EPA should receive judicial deference in its interpretation and implementation of the provisions. It is possible that EPA could confront arguments that 8(b)(3)(A)(iii), 8(b)(3)(B)(i), or 8(b)(3)(B)(ii) resolve various naming questions in industry's favor, but EPA's position would likely be that 8(b)(3)(A)(iii) is inapplicable (paraffins/nanoscale materials/micro-organisms are not statutory mixtures); 8(b)(3)(B)(i) is inoperative (no triggering guidance exists); and 8(b)(3)(B)(ii) is also inoperative (no duplicate listings exist).

Counter-arguments could be raised, though. A significant uncertainty in these provisions is what statements on multiple nomenclature might be cited by various stakeholder groups as guidance, and argued to constrain EPA's discretion in developing follow-up guidance under 8(b)(3)(B)(i). EPA would argue that only *EPA guidance* qualifies, and presumably that any EPA statement addressing nomenclature would have to have been issued at a sufficiently high level within the Agency to qualify as guidance, but the drafting is not clear in this regard. In addition, the legislative history referenced above could undercut an EPA position that there are no guidance documents allowing for multiple nomenclature conventions, and that 8(b)(3)(B)(ii) is also inoperative because no duplicate listings exist.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/12/2016 7:51:12 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Quick q section 5

Got it - checking

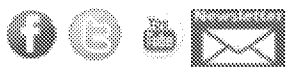
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 3:51 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Quick q section 5

How could we ensure that any extension associated with a 5(b) requirement to provide data be accounted for as an exception to the 90 day period after the notice is received? Can you suggest something for 5(a)(3)? Fast turnaround appreciated. I think we have something like this in 5(e) that is tied to receipt of the information – could that work? we don't want an automatic 90 day extension, we want to be sure that epa is not forced to make a decision w/o the info it needs or w/o enough time to review it,
Thanks

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 12, 2016 3:18 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Quick q section 5

Michal,
This responds to the TA request on the extension review.

We agree that it is helpful to clarify in 5(a)(3) that the 90 day review period is subject to extension under (c) and (e). But this text goes further, and introduces a further concept that the review period is automatically extended by 90 days upon receipt of information under (b) or (e). There does not appear to be such a provision currently under Section 5, so this is a substantive change, not just accounting for the fact that the 90 day review period can be extended under (c) or (e).

If you just wanted to clarify the status quo, you could say: "(3) Within 90 days of receipt of a notice under paragraph (1), and subject to any extensions of such review period pursuant to subsection (c) or (e), . . ."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 12:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Quick q section 5

There is a concern that 3(A) lead in does not account for the extension review.

Would this work?

(3) Within 90 days of receipt of a notice under paragraph (1), or of receipt of information submitted pursuant to subsection (b) or (e) that the Administrator finds sufficient to support the determination under subsection (a)(3)A), and subject to any extensions of such review period pursuant to subsection (c) or (e), ~~Before the end of the applicable period for review under paragraph (1),~~ and subject to section 18, the Administrator shall review a notice received under paragraph (1) and— …
?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/30/2016 10:51:23 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA Requests on House section 6(c)(1)(B) and Senate section 26(b)(4)(D)

David – This TA responds to the request regarding section 26(b)(4)(D) of the Senate proposal. EPA does not have any concerns with the language.

Regarding the TA request on House proposal section 6(c)(1)(B), we have potential concerns that need additional internal discussion. We will provide a response as soon as possible.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/27/2016 6:04:03 PM
To: McCarthy, David [David.McCarthy@mail.house.gov]; 'Couri, Jerry' [JerryCouri@mail.house.gov]; 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]; 'Fruci, Jean' [Jean.Fruci@mail.house.gov]
Subject: HEC TSCA TA on Nomenclature - revised statutory mixtures savings clause
Attachments: HEC TSCA TA on Nomenclature (4-26 version).docx; HEC.TSCA TA.Revised stat mixture savings clause.docx

HEC TSCA Team – The attached revised TA deals with the statutory mixtures savings clause. Also attached for reference is the earlier nomenclature TA that still stands except for the revisions on the statutory mixture savings clause.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Wednesday, April 27, 2016 11:47 AM
To: McCarthy, David <David.McCarthy@mail.house.gov>; 'Couri, Jerry' <JerryCouri@mail.house.gov>; 'Cohen, Jacqueline' <jackie.cohen@mail.house.gov>; 'Fruci, Jean' <Jean.Fruci@mail.house.gov>
Subject: HEC TSCA TA on Nomenclature (4-26 version)

HEC TSCA team – The attached TA responds to the request on section 8 nomenclature provisions. We are also working on the section 5 request.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all chemical substances described by the following category listings, when manufactured as described in such appendix, as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories:

"(I) Cement, Portland, chemicals, CAS No. 65997–15–1.

"(II) Cement, alumina, chemicals, CAS No. 65997–16–2.

"(III) Glass, oxide, chemicals, CAS No. 65997–17–3.

"(IV) Frits, chemicals, CAS No. 65997–18–4.

"(V) Steel manufacture, chemicals, CAS No. 65997–19–5.

"(VI) Ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) maintain the nomenclature conventions used by the Administrator for chemical substances as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

"(II) develop new guidance, as appropriate, that—

~~"(aa)~~ establishes equivalency between such ~~the~~ nomenclature conventions for chemical substances on the list published under paragraph (1)~~; and~~

~~"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).~~

"(ii) MULTIPLE CAS NUMBERS.—For a chemical substance determined by the Administrator to appear multiple times on the list in paragraph (1) under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(C) RELATIONSHIP TO SECTION 5.—

Commented [A1]: EPA TA: As discussed, this removes concerns that any nomenclature conventions at all might be cited.

Commented [A2]: EPA TA: This edit is to remove the statutory presumption that there is a problem that needs to be fixed by developing new guidance. It leaves the Administrator with discretion to consider whether there is a need for such guidance.

Commented [A3]: EPA TA: Suggest striking this subparagraph, since your objective in the savings clauses is to avoid allowing nomenclature arguments to be cited as a basis for avoiding new chemical review. This subparagraph is inviting just that.